PROMOTION OF PHARMACEUTICALS AND MEDICAL DEVICES

Authors: Att. M. Benjamin Gaw

GENERAL

1. What laws and codes of practice govern the promotion and advertising of pharmaceuticals and medical devices in your jurisdiction? Please also include any relevant industry and self-regulatory codes.

In Singapore, the advertising and promotion of pharmaceuticals and medical devices is generally regulated under the Health Products Act 2007 (HPA) and the following subsidiary legislation:

- The Health Products (Therapeutic Products) Regulations 2016;
- The Health Products (Medical Devices) Regulations 2010 (Medical Device Regulations); and
- The Health Products (Advertisement of Specified Health Products) Regulations 2016 (Advertisement of Specified HP Regulations).

Additionally, the regulatory authority with respect to medical devices, the Health Science Authority (HSA), has promulgated various guidance documents, the following of which are relevant to the advertisement and sales promotion of medical devices:

- GN-08-R2 Guidance on Medical Device Advertisements and Sales Promotion (HSA Guidance on MD Advertisement and Sales Promotion);
- Guidance for PHMCA/HCSA Licensees and Telemedicine Service Providers: Advertisement Controls of Health Products and Provision of Non-Promotional Information to the Public (HSA Guidance on Advertisement Controls);
- Explanatory Guidance to the Health Products (Advertisement of Therapeutic Products) Regulations (HSA Explanatory Guidance); and
- Guidance for PHMCA/HCSA Licensees and Telemedicine Service Providers: Advertisement Controls of Health Products and Provision of Non-Promotional Information to the Public.

The following industry and self-regulatory codes are also applicable:

- The Singapore Association of Pharmaceutical Industries (SAPI) Code of Conduct (SAPI Code) provides guidelines for the ethical promotion of pharmaceutical products by member companies. It covers interactions with healthcare professionals, clinical research, and the dissemination of product information.
- Similarly, the Asia Pacific Medical Technology Association's (APACMed) Code of Ethical Conduct for Interactions with Health Care Professionals (APACMed Code) offers guidance for the ethical marketing and promotion of medical devices. It addresses interactions with healthcare professionals and the marketing practices of member companies.
- The Singapore Code of Advertising Practice (SCAP), while not strictly speaking mandatory law, provides guidelines for ethical advertising through industry self-regulation and includes advertising guidelines for ethical advertising practices in Singapore and is enforced by the Advertising Standards Authority of Singapore (ASAS).

2. How is 'advertising' defined? If relevant in your jurisdiction, what is the difference between promotion and advertisement of pharmaceuticals? Of medical devices?

Under the HPA, 'advertisement' means the publication, dissemination, or conveyance of any information for the purpose of promoting, whether directly or indirectly, the sale or use of that health product through any means or in any form, including the following:

- publication in a newspaper, magazine, journal, or other periodical;
- display of posters or notices;
- circulars, handbills, brochures, pamphlets, books or other documents;
- letters addressed to individuals or bodies corporate or unincorporated;
- photographs or cinematograph films;
- sound broadcasting, television, the internet, or other media;
- public demonstration of the use of the health product; or
- offer of trials to members of the public.

On the other hand, while not defined under the HPA, in the respective guidance documents published by HSA (ie, the HSA Guidance on MD Advertisement and Sales Promotion and HSA Explanatory Guidance), 'sales promotion' means any advertisement in the form of a sales campaign (including door-to-door sales), exhibition, competition or any activity meant to introduce, publicise or raise the profile or public awareness or visibility of any therapeutic product for the purpose of promoting the sale or use of the product.

3. Which are the regulatory and supervisory authorities that regulate and enforce the promotion and advertisement of pharmaceuticals and medical devices? What is the relationship, if any, between any self-regulatory process and the supervisory and enforcement function of the competent authorities?

As mentioned in the response to Question 1, the regulation and enforcement of the promotion and advertisement of pharmaceuticals and medical devices in Singapore is carried out by the HSA. The HSA, operating under the Ministry of Health (MOH), is the central regulatory body tasked with ensuring compliance with the HPA and its subsidiary legislations. As a statutory entity, the HSA enjoys significant independence and control over its activities. However, it typically aligns its operations with the government's policy guidelines.

4. Are there other product types that fall under the same regulations on promotion (and advertisement) as pharmaceuticals, such as food supplements, special nutritional products? If so, are there any special considerations for the promotion (and advertisement) of such other product types?

Pharmaceuticals are classified and regulated as a therapeutic product under the HPA.

Generally, therapeutic product is defined as substance which:

- is used for therapeutic, preventive, palliative, or diagnostic purposes;
- exerts an inherent effect either pharmacologically, chemically or by other physiological means, leading to its use for a therapeutic, preventive, palliative or diagnostic purpose;
- contains specific chemical and biological active ingredients.

It however excludes topical antiseptics, Chinese proprietary medicines, traditional medicines, homoeopathic medicines, health supplements, medicated oils and balms, medical devices, and mosquito repellents.

Where other product types fall under the above definition, they will similarly be regulated under the HPA as a therapeutic product. However, food supplements and special nutritional products are unlikely to be considered as therapeutic product.

CONSUMER MARKETING

5. Is it possible to promote (or advertise) all forms of pharmaceuticals and medical devices (eg, prescription only or professional use products) directly to the public? Are there restrictions on public promotion (advertisements) in your country and, if so, which ones?

Restrictions which apply to both pharmaceuticals and medical devices

Primarily, under the HPA:

- The advertisement must not represent the registered pharmaceutical and medical device as being usable for any purpose other than that for which it has been registered.
- Medical devices must not be advertised in a false or misleading way (ie, it falsely describes the medical device or gives any false information concerning the medical device, or it is likely to create an erroneous impression regarding the formulation, composition, design specification, quality, safety, efficacy or uses of the medical device).

Restrictions which apply to pharmaceuticals only

The following restrictions apply when advertising pharmaceuticals:

- Generally, the advertisements of pharmaceuticals must not be misleading. For example, it must not –
  - be likely to lead to a consumer of the specified health product self-diagnosing or inappropriately treating any serious disease by themselves;
  - give the impression that advice from a registered pharmacist or qualified practitioner on the use of the specified health product is not necessary;
  - give the impression that a medical consultation or surgical operation is not necessary if the specified health product is used;
  - encourage, or be likely to encourage, inappropriate or excessive use of the specified health product;

  - mislead, or be likely to mislead, directly or by implication or through emphasis, contrast or omission, any person with regard to the quality or efficacy of the specified health product.
- Any statement, assertion, certification, award or feature of uniqueness or prominence differentiating the pharmaceuticals from any other competing or similar pharmaceuticals must be substantiated by facts or evidence.
- An advertisement by a non-public sector person of pharmaceuticals must not explicitly or implicitly claim, indicate or suggest that the pharmaceuticals –
  - will prevent, alleviate or cure any (sign or symptom clinically attributable to) disease or condition as specified in the Third Schedule of the Advertisement of Specified HP Regulations, (which includes cancer, diabetes and hypertension etc);
  - has similar properties or characteristics to, or works as well as, a product that is commonly used for the purpose of treating any specified disease or condition.
- Prescription-only medicine may only be advertised by a public authority established by a public act for a public purpose or a person authorised by the Ministry of Health.
- In relation to advertisements of pharmaceuticals which have not been registered with the HSA –
  - it must be in the form of an article in a medical or scientific journal, review or publication;
  - it must be made in the course of providing or exchanging scientific or medical information at, and in accordance with the published programme or agenda of, a scientific conference or forum that is a private event; or
  - it must be made at a pharmaceutical trade fair, pharmaceutical trade exhibition, scientific conference or scientific forum that is a private event, for a pharmaceutical that is approved, licensed or registered in at least one country outside Singapore, and contain a statement that the specified health product is not registered in Singapore;
  - it may contain a representation concerning the intended purpose or efficacy of the specified health product, provided that the representation has been verified by objective evidence.

In relation to sales promotion of pharmaceuticals, the promotor must not:

- offer any prize as an inducement to purchase the specified health product;
- offer together with the specified health product –
  - any other health product; or
  - any medicinal product.
- offer any sample of the specified health product;
- distribute or give, or cause to be distributed or given, or assist in the distribution or giving of, any free sample of a specified health product to the public or any section of the public.

Restrictions which only apply to medical devices

The following restrictions apply when advertising medical devices:

- If the medical device is intended for direct delivery to the general public or for direct use by the general public, the advertisement shall not contain any statement concerning the intended use and efficacy of the medical device, unless such a statement has been verified by objective evidence.
- The advertisement of a medical device shall not contain any statement which explicitly or implicitly suggests that the use of the medical device is promoted or endorsed by the HSA.
- Any statement, assertion, certification, award or feature of uniqueness or prominence differentiating the medical device from any other competing or similar medical device must be substantiated by facts or evidence.
  - The facts or evidence required for substantiation include the identity of the certifying or awarding body and the date the certification or award was granted; or, in relation to any claim of historical precedence in the use or administration of the medical device for the purpose of medical treatment, information on the outcome of that use or administration of the medical device.
  - Claims such as ‘most popular’ and ‘number one sales’ must be verified and substantiated by relevant market data and such supporting data must be available and provided on request.
- ‘Professional use only’ medical devices should not be advertised to the general public.
- The advertisements shall not explicitly or implicitly claim, indicate or suggest that the medical device will prevent, alleviate or cure any disease or condition specified in the Second Schedule of the Medical Device Regulations, which includes blindness, cancer, paralysis or infertility.

6. Is promotion (and advertising) of pharmaceuticals and medical devices through the internet and social media regulated in your jurisdiction? If so, what are the rules and related restrictions?

The HPA's definition of 'advertisement' is broadly worded and includes advertisements on the internet and social media. Therefore, the same rules apply.

Additionally, the Guidelines for Interactive Marketing Communication & Social Media promulgated by the ASAS will also be applicable when advertising on social media. The key principles include the following:

- Identification of commercial messages – the foremost principle is that all marketing communication must be identified as such and distinguished from editorial or personal opinions. For example, where a connection exists between the endorser and the marketer of the product or service that may materially affect the weight or credibility of the endorsement, such a connection must be fully disclosed.
- Clarity of the offer and conditions – marketers should indicate clearly to consumers whether they will be charged a fee for the use of the services. Marketers should not charge consumers unless such a warning has previously been provided.
- Respect for consumers, competitors, public groups and review sites – marketers are encouraged to update their internal social media policies regularly to ensure that consumers are not subjected to a marketing communication that is not endorsed by the brand, such as marketing myths and false campaigns.
- Use of social engagement tools – marketers must not boost the user engagement of a website, a social media channel or their content through fraudulent means. Examples include the purchase of bulk 'likes', the creation of fake accounts and the use of programs which generate page views.

7. Must promotions (and/or advertisements) receive prior approvals from regulators before use and if so, what is the procedure (please provide a high-level description)?

Advertisements and promotions of pharmaceuticals and medical devices do not require prior approval from the HSA, but such advertisements must comply with the principles and requirements as stated in the HPA.

8. May information on unauthorised pharmaceuticals and/or off-label information be promoted (advertised)? If so, in what circumstances and under which modalities?

See response to Question 5, above.

9. What rules govern comparative advertisements? Is it possible to use another company's information (including brand name) as part of that comparison? If so, which information and under which conditions? Would it be possible to refer to a competitor's product or indication which has not yet been authorised in your jurisdiction?

In relation to pharmaceutical products, the Advertisement of Specified HP Regulations does not permit any comparison or contrasting of a pharmaceutical with any other named product or a brand thereof. However, comparison among pharmaceuticals within the same brand by the same company to highlight differences between the products is permissible.

On the other hand, there is no specific ban against comparative advertising of medical devices.

However, advertisements should also not denigrate or unfairly attack any other products, goods or services or other sectors of the industry. It is reiterated that any claims should not be misleading and must be substantiated and supported by objective evidence.

DEALING WITH HEALTHCARE PROFESSIONALS AND HEALTHCARE INSTITUTIONS

10. How are healthcare professionals defined in your jurisdiction? Is there any regulation that restricts promotional (advertisement) communications directed to healthcare professionals? If so, what are those restrictions?

In the context of the HPA, healthcare professionals generally refer to registered medical practitioners, registered dentists, enrolled nurses, registered nurses and registered midwives, or a person undergoing training with a view to becoming any of the aforementioned roles.

The rules applicable to consumer advertising generally also apply when advertising to healthcare professionals.

However, note that the following does not apply when advertising to such healthcare professionals:

- comparative advertising of pharmaceuticals is permissible;
- the advertisement of pharmaceuticals may make claims that it will prevent, alleviate or cure any (sign or symptom clinically attributable to) disease or condition as specified in the Third Schedule of the Advertisement of Specified HP Regulations;
- the advertisement of medical devices may make claims that it will prevent, alleviate or cure any disease or condition specified in the Second Schedule of the Medical Device Regulations; and
- advertising of prescription only pharmaceuticals and professional-use only medical devices may be made to healthcare professionals.

11. Are there specific rules governing promotional (and advertising) activity conducted virtually, including online interactions with healthcare professionals, virtual meetings and participation in virtual congresses and symposia?

There are no specific rules on such activities.

12. Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional (advertising) materials? If so, which ones and how may such endorsements take place?

Testimonials, support, endorsements, recommendations, or any compliment, accolade or positive assessment by healthcare professionals are not allowed.

13. Is it possible to provide healthcare professionals with samples of medicinal products? Of medical devices? If so, what restrictions apply? Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.

As mentioned in the response to Question 1, SAPI Code provides guidelines for the ethical promotion of pharmaceutical products by member companies, while the APACMed Code offers guidance for the ethical marketing and promotion of medical devices.

Under the SAPI Code, samples must not be given away as an inducement to purchase. Only reasonable quantities of samples, clearly identified as such, may be supplied to the healthcare professionals prescribing such products to familiarise them with the products, to enable them to gain experience of the product in their practice, or on request. Samples should not be sold.

Under the APACMed Code, members may provide samples of medical technology products to healthcare professionals free of charge for evaluation and demonstration purposes, provided that:

- they are not given or intended as an improper inducement;
- only reasonable quantities of evaluation products are supplied to healthcare professionals to familiarise them with the products and enable them to gain experience with the products in their practice;
- they are only provided in quantities and/or for a duration that is reasonably determined to enable adequate evaluation by the healthcare professionals;
- they are appropriately documented and accounted for by the member, including to minimise any risk of the healthcare professionals being able to benefit financially from the products; and
- if not meant for human use or diagnostics purposes, they are marked ‘Not for human use’ or ‘Not for diagnostic purposes’ or with similar language to indicate that the products are solely for demonstration purposes and that they cannot be sold or used for human clinical studies or routine patient management.

Both the SAPI Code and APACMed Code ban the offering of gifts and cash to healthcare professionals.

Generally, it is also worth noting that from the healthcare professional’s perspective, they should be cautious not to contravene any professional code of conduct which applies to them. For example, for medical practitioners must comply with the Singapore Medical Council Ethical Code and Ethical Guidelines (ECEG). Some relevant rules include Section H3, under which, medical practitioners must not let business or financial considerations influence the objectivity of their clinical judgment in their management of patients.

14. What rules govern the offering of hospitality to healthcare professionals?

The SAPI Code limits the provision of food items and drinks as a part of discussion may be provided to healthcare professionals during the course of day-to-day promotional activities to less than SGD20 per healthcare professional.

The SAPI Code states that food and drinks incidental to the main purpose of the organisation of events (ie, symposia, congresses and other promotional, scientific or professional meetings) can only be provided exclusively to participants of the event and if they are moderate and reasonable as judged by local standards. It should also not exceed the value of SGD150 per person per meal. Additionally, such hospitality must be coupled with the sharing of scientific or educational information of products and must be conducted in an appropriate venue which is conducive to the scientific or educational objectives and the purpose of the event.

With regard to the APACMed Code, it provides that members may support third party educational conferences by funding reasonable costs associated with healthcare professionals' reasonable travel and modest accommodation. However, such costs should not be reimbursed directly to individual healthcare professionals but paid directly to the conference organiser or qualified and reputable third party service providers.

15. Are donations made by permit/authorisation holders to healthcare institutions or organisations considered a promotional (advertising) tool? Is there a special regulation on donations?

Under the SAPI Code, donation to medical societies, hospitals or a clinic's social events are not allowed. However, member companies may provide monetary, used items or product donations strictly for charitable purposes and charitable organisations if they are:

- from an institution or organisation, not an individual healthcare professional;
- substantiated by written documentation of details of donation request and reasonable and justified in the light of the activity being funded; or
- able to withstand public scrutiny and given without the intent to receive any benefit in exchange.

Similarly, the APACMed Code provides that charitable donations may be made to bona fide non-profit entities, charitable organisations, missions supporting charitable projects, and to other organisations supporting charitable projects. Such donations must not be targeted to healthcare professionals, nor used as a reward for a healthcare professional using, recommending, purchasing, or prescribing a member's products or services. All charitable donations shall be appropriately documented.

16. Can pharmaceutical laboratories or medical device manufacturers or their licensees support scientific or educational meetings? If so, is there any difference between these two sectors from the perspective of rules on the promotion of products?

The SAPI Code permits member companies to support events which provide scientific or educational information and/or inform healthcare professionals about products.

Similarly, the APACMed Code states that members may provide or support training and education to healthcare professionals on product specific technology deployment, use, and application to facilitate the safe and effective use of medical technologies. When supporting third party healthcare professionals' education through grants to, or other support of, third party educational programmes, members must uphold the independence of medical education.

Please also see response to Question 14.

17. Please provide an overview of the rules around the industry and patient organisations' relationships, including funding.

Under the SAPI Code, the standards which govern interactions with patient organisations are similar to those which apply to interactions with healthcare professionals.

The following principles are also applicable:

- Declaration of involvement – member companies must ensure that the involvement of the member company and the nature of that involvement are clear from the outset. No member company may have the requirement that it is the sole funder of the patient organisation or any of its programmes.
- Written Documentation – any financial support or in-kind contribution provided to patient organisations must be subjected to written documentation setting out the nature of support, including the purpose of any activity and its funding.

- Events – member companies may provide financial support for patient organisation meetings provided that the primary purpose of the meeting is professional, educational, and scientific in nature, or otherwise supports the mission of the patient organisation. Member companies must ensure that the venue and location is appropriate and conducive to informational communication. Any meals or refreshments provided by a member company must be modest as judged by local standards.

The APACMed Code does not have specific rules that govern industry and patient organisations' relationships

18. Is it possible to delegate promotional (advertising) activities to a third party through a service agreement? If so, under which conditions? Is co-promotion regulated in your jurisdiction and if so, how?

Yes. However, please note that such third party will be subjected to the same rules outlined in the responses to Question 5 and Question 9, above.

19. Is it mandatory in your country to report transfers of value made by permit/authorisation holders to healthcare professionals?

There are no specific rules mandating healthcare professionals to report transfer of value from permit/authorisation holders.

ENFORCEMENT

20. What penalties and other sanctions are associated with violations related to product promotion (advertisement)? Do supervisory authorities actively impose penalties and other sanctions? Are these penalties and other sanctions announced publicly?

A breach of the HPA may result in a fine not exceeding SGD20,000 or to imprisonment for a term not exceeding 12 months, or to both.

Any person who contravenes the Medical Device Regulations shall be guilty of an offence and shall be liable to a fine not exceeding SGD5,000.

Additionally, with regard to pharmaceutical products, under the Advertisement of Specified HP Regulations, HSA has the power to require copies of advertisements by giving written notice. Any person who fails to comply with a written notice may be liable a fine not exceeding SGD10,000 or to imprisonment for a term not exceeding six months or to both.

21. Who is responsible for enforcement, and how strictly are the rules enforced? To what extent may competitors take direct action through the courts in relation to promotion (advertising) infringements?

HSA
As mentioned in the response to Question 1, the HPA is enforced by the HSA.

All complaints and feedback to be provided to the HSA should be directed to the Medical Advertisement and Compliance Monitoring Unit at HSA_MA@hsa.gov.sg.

Where the rules on advertisement under the HPA have been breached, the HSA may give any of the following orders to the advertiser:

- to stop the advertisement with immediate effect;
- to take reasonable measures to remove the offending advertisements that have been published/distributed; and/or
- to publish a corrective advertisement in a manner and containing information as per specified by the Authority, which may include, but not limited to –
  - the content of the corrective advertisement;
  - the medium where the corrective advertisement is to be published/broadcast; and
  - the duration for which the corrective advertisement is to be published/broadcast.

Where the offender does not comply with the above, the HSA may take such steps as it thinks reasonable and necessary to implement the requirements of the order and recover any costs and expenses reasonably incurred by it in so doing from that person. The offender may also be liable to a fine not exceeding SGD20,000 or to imprisonment for a term not exceeding 12 months or to both.

ASAS

Advertising complaints may also be made to the Chairman of ASAS, and all complaints should be in writing and accompanied by:

- a copy of the advertisement (eg, cutting of the press or magazine advertisement, full text of the radio, television or cinema commercial complained of);
- contact information, especially the postal address, of the complainant; and
- sufficient details of the complaint for ASAS to act.

The complainant has to also provide a written confirmation that it has paid the administrative fee according to the tariff published by ASAS before investigations/deliberations will begin.

ASAS may call on the complainant, the person complained against or any other person for information that ASAS deems relevant in assessing the advertisement complained of.

FUTURE DEVELOPMENTS

22. Are any significant developments in the field of pharmaceutical or medical device promotion (advertising) expected in the next year or so? Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

To our knowledge, there are none at the time of writing.