PROMOTION OF PHARMACEUTICALS AND MEDICAL DEVICES

Authors: Att. Jennifer Wang and Att. Edward Liu

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.

The primary laws and codes of practice are as follows:

Pharmaceuticals

- Pharmaceutical Affairs Act;
- Enforcement Rules of Pharmaceutical Affairs Act; and
- Code of Practice of International Research-Based Pharmaceutical Manufacturers Association (IRPMA) (the IRPMA COP).

Medical devices are governed by the Medical Devices Act and the Enforcement Rules of Medical Devices Act.

The above is not an exhaustive list. There are other detailed regulations or guidelines governing the promotion and advertising of pharmaceuticals and medical devices. We only list the primary laws.

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

- For pharmaceuticals, 'advertising' is the act of advertising the medical efficacy of pharmaceuticals by means of communications for the purpose of soliciting and promoting the sale thereof.
- For medical devices, 'advertising' is the act of publicising the therapeutic effect of medical devices by means of communications for the purpose of soliciting and promoting the sale thereof. Interviews, news reports, or propaganda containing information which implies or suggests the therapeutic effect of medical devices to solicit and promote sales shall be regarded as medical device advertisements.
- The laws and codes of practice governing the promotion and advertising of pharmaceuticals and medical devices have not defined promotion or specifically differentiated promotion from advertisement.

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?

- In Taiwan, there are different authorities which regulate and enforce the promotion and advertisement of pharmaceuticals and medical devices.
- An advertisement of pharmaceuticals or medical devices can be advertised only after the authority has reviewed and approved the advertisement's content. Which authority has the power to review and approve a specific advertisement for pharmaceutical or medical device depends on the registered address of the pharmaceutical or medical device firm applying for the advertisement approval. If the registered address of a manufacturer or dealer of the advertised pharmaceutical or medical device is within the Taipei City, the New Taipei City, the Taoyuan City, the Taichung City, the Tainan City or the Kaohsiung City, the authority shall be the Department of Health of such city governments. If the registered address of a manufacturer or dealer of the advertised pharmaceutical or medical device is outside the six cities mentioned above, the authority shall be the Taiwan Food and Drug Administration (the TFDA).
- If a manufacturer or dealer of a pharmaceutical or medical device violates any laws or regulations governing the promotion and advertising of pharmaceuticals or medical devices, the supervisory authority that has the power to punish the violator shall be the Department of Health of the city or local government where the violator's registered address is.
- As there is no law specifically authorising the authority to impose penalties for non-compliance with the IRPMA COP, the IRPMA COP is not enforced by the authority. However, IRPMA does set out the Administrative Operation Procedures of the IRPMA COP, which stipulate the penalties for violating the IRPMA COP.

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?

In Taiwan, separate laws apply to other products. There are other specific laws regulating food, health food, cosmetics, etc, and they each have their own regulations on advertisement.

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?

Not all forms of pharmaceuticals and medical devices can be promoted directly to the public in Taiwan. The following are some restrictions on public promotion or advertisement of pharmaceuticals and medical devices:

- According to Article 33 of the Pharmaceutical Affairs Act, the salespersons employed by a pharmaceutical firm shall only sell medicaments to pharmaceutical firms, health and medical care institutions, or medical research institutions.
- According to Article 67 of the Pharmaceutical Affairs Act, the advertisements of (a) prescription medicaments or (b) medicaments designated by the central competent authority shall only be published in academic medical journals.
- According to Article 44 of the Medical Devices Act, the advertisements of medical devices that (a) shall be used by healthcare professionals or (b) designated by the central competent authority shall only be made in medical publications or media for healthcare professionals or the related medical academic activities in which only they can participate.

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 general principle is that advertisement of pharmaceuticals/medical devices, including those through the internet and social media, shall be reviewed and approved by the authority prior to its advertising (please see the response to Question 3 for details). Sales through the internet and social media are not discussed here.

Moreover, for pharmaceuticals, if the pharmaceutical permit holder only posts information about its medicinal products, such as ingredient names, product names, permit number, indications, side effects, contraindications, and warnings on its official website in accordance with the contents of the approved package inserts, and also posts pictures of the outer boxes and the physical appearances of the medicinal products at the same page with the information mentioned above, such act shall not constitute 'advertising'. Consequently, no prior approval from the competent authority is required for pharmaceuticals firms to post product information on their own websites if the contents comply with the law. The same rule also applies to medical devices.

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)?

The procedure is as follows:

- The applicant submits the application form, advertisement contents, medicament (or medical device) licence, business licence as a pharmaceutical (or medical device) firm and application fee to the competent authority.
- The competent authority reviews the application documents.
- If the application is approved, the competent authority will send the advertisement approval document to the applicant, with a specific number indicated, so that such number can be included in the advertisement.

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

Information about unauthorised pharmaceuticals cannot be promoted (advertised). Texts and images used in a pharmaceutical advertisement shall be limited to the name of the medicament, its dosage form, prescription content, usage quantity, usage method, efficacy, guidelines, and packaging, and the name and address of the manufacturer, as approved by the central competent health authority.

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?

The Fair Trade Act, Pharmaceutical Affairs Act, Medical Devices Act, and Enforcement Rules of Medical Devices Act govern comparative advertisements relating to pharmaceuticals or medical devices.

It is possible to use another company's information (including brand name, but not trademarks) as part of the comparison, only after such advertisement content is approved and only to the extent information is approved by the competent authority. For an advertisement involving comparative content, relevant supporting documents should be submitted for the competent authority's review. The comparisons should be made on the same basis and the comparative information should be disclosed in the advertisement. Furthermore, even though a comparative advertisement does not explicitly point out a specific target for comparison, it may still constitute an improper method of advertising medicinal products regulated under the Pharmaceutical Affairs Act. This may be the case where the comparative advertisement shows content of exclusivity that may degrade the products of competitors in the same industry and cause customers to reduce or refuse to trade with such competitors.

Regarding comparative advertisements of medical devices, the Enforcement Rules of Medical Devices Act specifically states that a comparative advertisement shall not be approved if it fails to use a fair, objective, and appropriate comparison basis to compare the effectiveness or therapeutic effect.

The law does not specifically allow advertisements to refer to a competitor's product or indication which has not yet been authorised in Taiwan. Since advertisements need to be reviewed and approved by the competent authority before being published or broadcast, this question may be subject to the competent authority's scrutiny and discretion.

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?

According to the Medical Care Act, medical personnel are defined as physicians (including physicians, traditional Chinese medical physicians and dentists), pharmacists, professional nurses, physical therapists, occupational therapists, medical examination technologists, medical radiation technologists, dietitians, professional midwives, clinical psychologists, counselling psychologists, respiratory therapists, speech therapists, hearing specialists, dental technicians, opticians, assistant pharmacists, nurses, midwives, physical therapy assistants, occupational therapy assistants, medical examination technicians, medical radiological technicians, assistant dental technicians, optical technicians, and other personnel with professional medical certificates issued by the central competent authority.

There is no law that specifically restricts promotional (advertisement) communications directed 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 governing such activities. The authority has not expressly permitted the promotion or advertisement of medicaments or medical devices by online interactions with healthcare professionals, virtual meetings and participation in virtual congresses and symposia. Further, the authority has held in one case that, promotion or advertising activity conducted as seminars, promotional events or exhibitions was deemed as promoting medicaments by improper means.

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?

The law does not specifically prohibit or lay down any detailed restrictions to the inclusion of endorsements by healthcare professionals in promotional (advertising) materials. Since advertisements need to be reviewed and approved by the competent authority before being published or broadcast, this question may be subject to the competent authority's scrutiny and discretion on a case-by-case basis.

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.

Providing healthcare professionals with samples of medicinal products and/or medical devices is allowed under the Regulations on Management of Medicament Samples and Gifts.

In terms of a medicinal product, it shall be for the purposes of research or trial, a teaching hospital's diagnosis and treatment of patients with critical or catastrophic illness, or for purposes of public safety or public health or significant disasters. In terms of a medical device, it shall be for the purposes of research or trial or for specific exhibitions or demonstrations. The health institution or health professional shall not sell, transfer, or use such samples for other purposes.

According to the Fair Trade Act, an enterprise shall not compete for trading opportunities by the improper offering of gifts. According to IRPMA COP, payments in cash, cash equivalents, personal service[1] or gifts for personal benefit[2] must not be provided or offered to healthcare professionals.

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

According to the IRPMA COP, for events and meetings,

- Hospitality shall be limited to the refreshments and/or meals incidental to the main purpose of the event and can only be provided exclusively to participants of the event and such hospitality shall be moderate and reasonable as judged by local standards.
- The expenses of hospitality should be limited to refreshments and/or meals incidental to the main purpose of the event and should not exceed NT$3,500 per person per day. For overseas events, the principle is that the expense amount should not exceed NT$3,500 per person per day. However, if the expense limits of the international/local regulations of the visiting countries exceed NT$3,500 per person per day, the regulations of the visiting place can be followed.
- No entertainment or other leisure or social activities should be provided or paid for.
- The hospitality provided should not exceed what healthcare professional recipients would normally be prepared to pay for themselves.

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?

According to the IRPMA COP, donations and educational grants must be clearly separated from business. The intention of making a donation or providing an educational grant must not be associated with influencing the purchasing, prescribing and pricing of medicines. Donations and educational grants must not be given to personal accounts or the accounts of individual departments of hospitals. Donations or educational grants must only be given to government registered medical institutions, medical societies, associations and foundations. The IRPMA strongly recommends each member company establishes a proper review and approval process for donations and educational grants.

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?

No law specifically prohibits pharmaceutical laboratories, medical device manufacturers or their licensees from supporting scientific or educational meetings. However, for pharmaceutical laboratories that are a member of the IRPMA, the IRPMA COP provides detailed regulations on for example: the product information which can be disclosed in such meetings, the location of such meetings, service fees paid to healthcare professionals, travel reimbursement, and flight tickets provided for such meetings.

According to the IRPMA COP, the purpose and focus of all symposia, congresses and other promotional, scientific or professional meetings for healthcare professionals organised or sponsored by a member shall be to provide scientific or educational information and/or to inform healthcare professionals about products.

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

According to the IRPMA COP:

[1] Any service unrelated to the health professional's profession and that confer a personal benefit to them.
[2] Such as sporting or entertainment tickets, electronic items, etc.

- Its members shall interact with patient organisations in compliance with the IRPMA COP and respect such organisations' independence. No member of the IRPMA can be the sole funder of a patient organisation or any of its programmes.
- A member providing financial support or in-kind contribution to patient organisations must have written documentation stating the nature of support, including the purpose of any activity and its funding.
- Besides helping a patient organisation achieve its purpose of establishment, a member may also provide financial support for a meeting held by a patient organisation only when it is professional, educational, and scientific in nature. The member shall ensure that: (1) the venue and location of the meeting are conducive for communication; and (2) the meals and refreshments provided are modest as judged by local standards.

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?

As explained above, an advertisement for pharmaceuticals/medical devices can only be advertised after the authority has reviewed and approved its content. The applicant of such an application shall be the pharmaceutical or medical device firm that holds the permit for the medicament or medical device to be advertised. Therefore, generally speaking, the advertiser shall always be the pharmaceutical or medical device firm that holds the permit, not any third party who is delegated to provide advertising service through a service agreement. However, the permit holders can commission a media enterprise to publish or broadcast the pharmaceuticals/medical devices advertisement approved by the competent authority.

When one advertisement contains multiple medicinal products whose licences are held by different pharmaceutical firms, the advertisement application can be submitted by one of the pharmaceutical firms, with the other firms' authorisation.

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

The permit/authorisation holders are not obligated to report transfers of value made by them to healthcare professionals under the applicable laws. For healthcare professionals, health institutions may enact a code of conduct requiring them to report these. In addition, healthcare professionals employed by public hospitals administered by the Ministry of Health and Welfare are considered civil servants and shall report these in accordance with laws and regulations applicable to civil servants.

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?

As the advertisements of medicaments/medical devices are highly regulated in Taiwan, different penalties and sanctions are associated with various violations related to product advertisements. Most penalties are fines. If the Pharmaceutical Affairs Act or the Medical Devices Act is violated, the violator will be fined a sum ranging from NTD60,000 to NTD25,000,000 (approx US$1,850 to US$770,000), depending on the specific article violated and how many times it violated that same article. If the Fair Trade Act is violated, the fine ranges from NTD50,000 to NTD50,000,000. If the making or disseminating a false statement that is capable of damaging the business reputation of another for the purpose of competition is made, it may even incur criminal liability for the violator.

In Taiwan, the supervisory authorities impose penalties and other sanctions. The supervisory authorities may take the initiative to conduct random checks on advertisements for non-compliance or be alerted to a pharmaceutical/medical device firm's non-compliance by its competitors or any citizen. In 2023, 39 cases were issued a fine by the Taipei City Government for violating the Pharmaceutical Affairs Act or the Medical Devices Act.

The violated product, the name of the violator, the regulations violated, and the amount of fines are published for violations of the Pharmaceutical Affairs Act or the Medical Devices Act. Penalties or sanctions for violations of the Fair Trade Act are also published.

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?

It depends on the law being violated. If the pharmaceutical/medical device firm violates the Pharmaceutical Affairs Act/Medical Devices Act, the health authority is responsible for enforcement (please see the response to Question 3). If it violates the Fair Trade Act, the Fair Trade Commission is responsible for enforcement. If the authority has confirmed the pharmaceutical/medical device firm's violation, it will enforce the rules according to the applicable law(s).

When an advertisement: infringes a competitor's trademark(s); or violates the Fair Trade Act and infringes the rights of a competitor, the competitor may take direct action through the courts to stop the infringement and seek compensation from the infringer.

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?

This may not be a significant development, but the TFDA published the draft amendment of the Government Fees Standard of Reviewing Pharmaceutical Advertisements on 15 January 2024. The government fees charged for the application of the review and approval of medicament advertisements are expected to increase in 2024.

With the growing popularity of social media, which has become an essential communication channel for almost everyone, users often illegally post advertisements for pharmaceuticals/medical devices because they are unaware of the law. However, due to the high degree of anonymity on the internet and the difficulty in finding the real perpetrators, the authorities may wish to strengthen the management of internet advertising by amending the law in future.