

<b>PROMOTION OF PHARMACEUTICALS AND MEDICAL DEVICES</b>
<b>Authors:</b> Yuwadee Thean-Ngarm
<b>GENERAL</b>
<b>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.</b>
<p><b>Pharmaceuticals</b></p> <p>Myanmar’s National Drug Law No 7 of 1992 (the ‘National Drug Law’) and Notification No 7/1993 on Drug Labeling issued by the Ministry of Health (‘Notification on Drug Labeling’) govern the promotion and advertising of pharmaceuticals in the jurisdiction. Additionally, the Medical Ethics for Medical Professions established by the Myanmar Medical Council in July 2003 (the ‘Medical Ethics Guideline’) provide self-regulatory codes for this industry.</p> <p><b>Medical devices</b></p> <p>Because Myanmar has not yet implemented the Medical Device Law, the Food and Drug Administration Myanmar (the ‘FDA Myanmar’) uses the Association of Southeast Asian Nations (ASEAN) Medical Device Directive and the Administrative Guideline issued by the Myanmar FDA from time to time, as well as the regulations issued by the FDA Myanmar for medical devices from time to time to govern the promotion and advertising of medical devices. The provisions of the Consumer Protection Law No 9 of 2019 (the ‘Consumer Protection Law’) also regulate the promotion and advertisement of medical devices.</p>
<b>2. How is ‘advertising’ defined? If relevant in your jurisdiction, what is the difference between promotion and advertisement of pharmaceuticals? Of medical devices?</b>
<p><b>Pharmaceuticals</b></p> <p>There are two main definitions of ‘advertising’ under the National Drug Law and Consumer Protection Law. Pharmaceuticals fall within both definitions.</p> <p>According to the National Drug Law, advertising means carrying out measures, directly or indirectly, to inform the public with the intention of promoting the distribution and sale of drugs.</p> <p>The Consumer Protection Law defines an advertisement as an act aimed at informing consumers about goods or services through written, oral, visual, auditory or other means. This law further defines sales promotion as an act conducted in one or more methods to increase consumer awareness and the utilisation of consumer goods or services.</p> <p><b>Medical devices</b></p> <p>The definitions of ‘advertising’ and ‘sales promotions’ provided in the Consumer Protection Law apply to all consumer goods and services, including medical devices. In this regard, there are no separate definitions applicable to medical devices due to the absence of separate laws governing medical devices in Myanmar.</p>
<b>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?</b>
<p><b>Pharmaceuticals</b></p> <p>The FDA Myanmar, operating under the Ministry of Health, serves as the primary regulatory and supervisory authority responsible for regulating the promotion and advertisement of pharmaceuticals. The Department of Consumer Affairs, Ministry of Commerce Myanmar, also holds supervisory authority to regulate the promotion and advertisement of pharmaceuticals. There is no mandatory self-regulatory process and the enforcement is by the supervisory authority.</p> <p><b>Medical devices</b></p>

The FDA Myanmar together with the Department of Consumer Affairs are the supervisory authorities in charge of overseeing the promotion and advertisement of medical devices.

**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?**

Depending on the classification of the particular product, the same regulations applicable to the advertising of pharmaceuticals may govern food and health supplements, as well as special nutritional products. If the food and/or health supplement falls into the category of pharmaceuticals, the same regulations apply. However, if the product is classified merely as a food product, the regulations under the National Food Law are applicable. Further to these regulations, on 14 February 2020, the FDA Myanmar announced regulations governing the promotion and advertising of food and/or health supplements during the application for the Import Recommendation (IR) of such products. In addition, all of these products are required to follow the provisions of the Consumer Protection Law and its regulations.

**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?**

**Pharmaceuticals**

Over-the-counter drugs can only be advertised to the public after obtaining a Drug Registration Certificate from the FDA Myanmar. Prescription drugs are not allowed to be advertised to the public, but may be advertised to healthcare professionals, dentists, veterinarians, nurses, pharmacists and medical persons, after obtaining a Drug Registration Certificate from the FDA Myanmar.

**Medical devices**

It is possible to promote/advertise medical devices in line with the requirements outlined in the Consumer Protection Law and regulations.

Restricted advertisements of medical devices per section 63 of the Consumer Protection Law are as follows:

- fraudulent advertisements related to the quality, quantity, ingredients, mode of use, price, rate of service, warranty and time needed to deliver the goods or services;
- advertisements including false information, and that are not informative about the risk of using in respect of goods or services;
- advertisements using any person or event without the permission of the person concerned; and
- advertisements that are inconsistent with existing laws or ethics.

Restricted promotions of medical devices per section 64 of the law are as follows:

- offering to sell the goods with a special price within a period without any plan to sell at the advertised amount or quality within the specified period;
- offering to sell the goods by pledging to pay a bonus or to provide free services that cannot actually be provided; and
- offering to sell the goods or services in any way that disturbs the consumer physically or mentally.

**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?**

**Pharmaceuticals**

The promotion and advertising of pharmaceuticals through the internet and social media are not regulated specifically. However, the prohibitions under the National Drug Law cover promotion and advertising through all channels, including the internet and social media. Should the FDA Myanmar become aware of the advertising or promotion of pharmaceuticals on the internet and/or social media that does not comply

with applicable laws, it can issue a warning to the Drug Registration Certificate holder and take any additional actions provided for in relevant regulations.

**Medical devices**

The promotion and advertising of medical devices through the internet and social media are also not regulated specifically. Promotions and advertisements through social media are permitted, as long as they comply with the provisions of the ASEAN Medical Device Directive, the Administrative Guideline issued by the Myanmar FDA, the regulations issued by the FDA Myanmar for medical devices and the Consumer Protection Law. Please see our response to Question 1 regarding 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)?**

**Pharmaceuticals**

After approval is obtained for the registration of the pharmaceutical product from the FDA Myanmar, the product may be advertised or promoted subject to relevant criteria for over-the-counter and prescription drugs. However, if the promotion or advertisement is to be conducted at government hospitals, additional prior approval from the relevant state/region public health offices or the Ministry of Health, in accordance with the procedural requirements of government hospitals, is mandatory.

In short, an entity or individual wishing to promote or advertise products at government hospitals is required to submit an application with a cover letter detailing the product information and the promotion plan to the state/region public health offices or the Ministry of Health, depending on the location of the government hospital(s) and the scale of the promotion plan.

**Medical devices**

There are no separate provisions in Myanmar law requiring prior approval for the promotion and advertising of medical devices. These promotions and advertisements are governed by the provisions of the ASEAN Medical Device Directive, the Administrative Guideline issued by the Myanmar FDA from time to time, the regulations issued by the FDA Myanmar for medical devices, and the Consumer Protection Law.

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

The National Drug Law strictly prohibits the promotion or advertisement of unauthorised pharmaceuticals and/or off-label information.

**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?**

**Pharmaceuticals**

According to the National Drug Law, the Notification on Drug Labeling and the Consumer Protection Law, using another company's information (including brand names) as part of a comparison is not permitted.

The following prohibitions apply to the advertising of pharmaceuticals:

- advertising the use of trial drugs that have not been approved for use;
- comparative advertising using other drugs;
- advertising drugs by providing samples, money or gifts; and
- before and after use comparisons.

**Medical devices**

Comparative advertisements for medical devices are permitted, subject to the restrictions set out in the Consumer Protection Law. Section 63 of the Consumer Protection Law sets out the following restrictions on the advertising of goods and services, including medical devices:

- fraudulent advertisements concerning the quality, quantity, ingredients, mode of use, price, rate of service and delivery time of the goods or services;

<ul style="list-style-type: none"> <li>• fraudulent advertisements related to the warranty of goods or services;</li> <li>• advertisements containing false information in respect of goods or services;</li> <li>• advertisements that fail to provide information about the risk associated with the use of the goods or services;</li> <li>• advertisements using any person or event without the permission of the person concerned; and</li> <li>• advertisements that are inconsistent with existing laws or ethics in Myanmar.</li> </ul>
<b>DEALING WITH HEALTHCARE PROFESSIONALS AND HEALTHCARE INSTITUTIONS</b>
<b>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?</b>
<p>Healthcare professionals from various fields are defined under various laws, as follows:</p> <ul style="list-style-type: none"> <li>• Registered Medical practitioners are defined as ‘a person whose name has been entered in the medical practitioners’ registration list and who has been issued the medical practitioner registration certificate’ under section 2 (g) of the Myanmar Medical Council Law 2015.</li> <li>• Dentists are defined as ‘a person whose name has been entered on the registration list and who has been issued the dentist registration certificate by the Myanmar Dental Council Law’ under section 2 (e) of the Myanmar Dental Council Law 2011.</li> <li>• Nurses are defined as ‘the person who received a nurse registration certificate or licence issued by the council under this law’ under section 3(c) of the Myanmar Nurse and Midwife Council Law 2015.</li> </ul> <p>Restrictions pertaining to direct communication with healthcare professionals for the promotion or advertisement of pharmaceuticals under the National Drug Law and the Notification on Drug Labeling include promoting or advertising only registered products. Additionally, the President’s Office Guidelines on Accepting Gifts issued in 2016 (the ‘President’s Office Guidelines on Accepting Gifts’) regarding the provision of gifts and money in relation to promotions or advertising states that accepting gifts and money more than the amount specified in the guideline is prohibited. Please see the specified amount in our response to Question 13.</p>
<b>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?</b>
<p><b>Pharmaceuticals</b></p> <p>There are no specific rules governing promotion or advertising activities conducted virtually, including online interactions, virtual congresses and symposia. All interactions with healthcare professionals for the promotion or advertising of pharmaceuticals, whether physical or virtual communication, must comply with the National Drug Law, the Notification on Drug Labeling and the President’s Office Guidelines on Accepting Gifts.</p> <p><b>Medical devices</b></p> <p>There are no specific rules governing promotion or advertising activities conducted virtually, including online interactions, virtual congresses and symposia. All communication with healthcare professionals for the promotion or advertising of medical devices, whether physical or virtual, must be in accordance with the President’s Office Guidelines on Accepting Gifts.</p>
<b>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?</b>
<p><b>Pharmaceuticals</b></p> <p>The Notification on Drug Labeling prohibits the inclusion of endorsements by healthcare professionals in the promotion or advertising of pharmaceuticals.</p> <p><b>Medical devices</b></p> <p>There are no specific restrictions on including endorsements by healthcare professionals in the promotion or advertising of medical devices in Myanmar.</p>

**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.**

It is permissible to provide a sample medicinal product and/or medical devices to healthcare professionals for both over-the-counter medicines and prescriptions, provided the samples are of registered products.

As for providing gifts or monetary donations to healthcare professionals, the President's Office Guidelines on Accepting Gifts outlines restrictions applicable to public servants. Anti-corruption concerns related to monetary and non-monetary contributions to healthcare professionals who are public servants, such as government doctors, are addressed in this guideline. This guideline strictly prohibits civil servants from accepting individual gifts exceeding MMK 25,000 (approximately US\$12) in value, and the total value of gifts received from an individual or organisation shall not exceed MMK 100,000 (approximately US\$48) in a single year. In this regard, 'gifts' are defined to include money, gold, silver, air tickets, hotel stays, meals and golf club membership fees. The following exceptions are provided for:

- where gifts are given during recognised religious holidays, such gifts must not exceed MMK 100,000 (approximately US\$48) in value;
- gifts provided on account of a familial or personal relationship; and
- gifts from foreign governments worth not more than MMK 400,000 (approximately US\$190) are allowed for diplomatic reasons, as well as money for travel, medical expenses or scholarships.

Please also refer to Code 27 in our response to Question 14.

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

The President's Office Guidelines on Accepting Gifts govern the offering of hospitality to healthcare professionals who are civil servants. Hospitality for healthcare professionals in the private sector is regulated by the Medical Ethics Guideline, the relevant sections of which are as follows:

**Code 27**

*Accepting gifts or other inducements*

The medical practitioner should not ask for or accept any material gifts or loans, except those of insignificant value, from companies that sell or market drugs or appliances. The medical practitioner must not ask for or accept fees for agreeing to meet sales representatives.

**Code 28**

*Hospitality*

The medical practitioner may accept personal travel grants and hospitality from companies for conferences or educational meetings, as long as the main purpose of the event is educational. The amount that the medical practitioner receives must not be more than he/she would normally spend himself/herself. The objective of the travel grants hospitality should not influence the use of their products.

**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?**

This will depend on the purpose of the particular donation, as there is no criteria set by law regarding which kind of donations are considered promotional/advertising tools. Other than the regulations mentioned above, the law does not specifically outline any additional special regulations on donations.

**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?**

Pharmaceutical laboratories and medical device manufacturers or their licensees are permitted to support scientific or educational meetings with healthcare professionals. The relevant regulations for both of these sectors are contained in the President's Office Guidelines on Accepting Gifts for civil servant healthcare professionals and the Medical Ethics Guideline for the private sector.

**17. Please provide an overview of the rules around the industry and patient organisations'**

<b>relationships, including funding.</b>
There are no specific regulations governing the relationship between the industry and patient organisations, including funding within the industry.
<b>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?</b>
It is possible to delegate promotional and/or advertising activities to a third party through a service agreement in accordance with the terms and conditions set out by parties, subject to the Myanmar Contract Act 1872.
There are no specific regulations on co-promotion in Myanmar.
<b>19. Is it mandatory in your country to report transfers of value made by permit/authorisation holders to healthcare professionals?</b>
In Myanmar, it is mandatory to report transfers of value made by permit/authorisation holders to healthcare professionals under certain circumstances. Specifically, if the permit/authorisation holder is the wholesale/retail licence holder (licence holder) for selling pharmaceuticals under Notification No 6/1993 on [wholesale/retail selling licence of drugs] issued by the Ministry of Health, the FDA Myanmar is required to record the transfers of value of controlled pharmaceuticals. When instructed by the FDA Myanmar to present these records, the licence holder is obligated to comply accordingly. The retention period for these records is two years from the date of their creation.
<b>ENFORCEMENT</b>
<b>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?</b>
<p><b>Pharmaceuticals</b></p> <p>Pursuant to section 17 (b) of the National Drug Law, a Drug Registration Certificate holder is required to abide by the orders and directives regarding product promotions and advertisements issued by the Ministry of Health and/or the Board of Authority.</p> <p>Section 20 of the National Drug Law stipulates penalties for violation of section 17. It states that on conviction, a violator may be punished with a fine ranging from a minimum of MMK 5,000 (approximately US\$2.3) to a maximum of MMK 50,000 (approximately US\$24) or with imprisonment for a term that can extend up to one year, or both.</p> <p>The supervisory authority is likely to actively impose penalties and other sanctions. However, not all penalties and sanctions have been publicly announced.</p> <p><b>Medical devices</b></p> <p>No medical device laws have yet been implemented in Myanmar. As a result, promotions and advertisements of medical devices are governed by the Consumer Protection Law, which provides for the following penalties:</p> <ul style="list-style-type: none"> <li>• The violation of any prohibition contained in sections 63 and 64 of the Consumer Protection Law is punishable with imprisonment for a term not exceeding six months or with a fine not exceeding MMK 2m (approximately US\$953).</li> <li>• If the same violation is committed again, it is punishable with imprisonment for a term not exceeding one year or with a fine not exceeding MMK 10m (approximately US\$4,762) or with both.</li> </ul> <p>Nonetheless, not all these penalties/sanctions have been announced publicly.</p>
<b>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?</b>
<p><b>Pharmaceuticals</b></p> <p>The FDA Myanmar, operating under the Ministry of Health, serves as the primary enforcement authority</p>

for promotions and advertisements of pharmaceuticals. The Department of Consumer Affairs, Ministry of Commerce Myanmar, also holds enforcement authority.

Consumers and/or competitors may lodge complaints regarding an infringement of regulations on promotions and advertisements with the FDA Myanmar, the Department of Consumer Affairs and/or the courts directly. The licence holder will be liable for infringements.

**Medical devices**

The FDA Myanmar and the Department of Consumer Affairs are the enforcement authorities for the promotion and advertisement of medical devices.

Currently, the investigation of infractions and the imposition of penalties for breaches thereof are infrequent in Myanmar owing to a disconnect between regions of the country.

Consumers and/or competitors may lodge complaints regarding an infringement of regulations on promotions and advertisements with the FDA Myanmar, the Department of Consumer Affairs and/or the courts directly. The import authorisation holder will be liable for infringements.

**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?**

**Pharmaceuticals**

At present, accurately predicting significant developments in the field of pharmaceutical promotion/advertising within the next year is not feasible. It is crucial to note that Myanmar is under a State of Emergency, which means that regulations or restrictions can be imposed, amended, deleted or replaced at any time, often at short notice.

**Medical devices**

We anticipate the enactment of the Medical Devices Law in Myanmar, currently undergoing the approval process within the legislative authority. Once this law is implemented, significant changes to medical device promotions and advertisement are expected. As stated above, Myanmar is currently under a State of Emergency, which may impact the timing and implementation of these regulatory changes.