PROMOTION OF PHARMACEUTICALS AND MEDICAL DEVICES

Authors: Dino Santaniello

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 advertising and promotion of pharmaceutical products and medical devices in Laos are primarily governed by the Decision on the Management of Advertisement of Food, Drugs, and Medical Equipment No 1494/MOH, dated 6 July 2016 (the 'Decision on the Management of Advertisement of Food, Drugs, and Medical Equipment'). In addition to this, the Decision on Advertisement of Goods and Services on Mass Media No 530, dated 12 June 2023 (the 'Decision on Advertisement of Goods and Services on Mass Media'); the Law on Drugs and Medical Products No 07/NA, dated 21 December 2011 (the 'Law on Drugs and Medical Products'); the Law on Healthcare No 48/NA dated 20 November 2023 (the 'new Law on Healthcare'); the Law on Consumer Protection No 02/NA, dated 30 June 2010 (the 'Law on Consumer Protection'); and the Law on Business Competition No 60/NA, dated 14 July 2015 (the 'Law on Business Competition') are applicable. These regulations contain more general provisions and are not specific to promotions or advertisements.

There is no code of conduct specific to the pharmaceutical product and/or medical device industries.

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

The Decision on the Management of Advertisement of Food, Drugs, and Medical Equipment does not define advertising. Similarly, the Decision on Advertisement of Goods and Services on Mass Media also lacks a clear definition of advertising, providing instead only for 'advertising on mass media', which is defined as the dissemination of communications concerning goods and services via traditional media, such as newspapers, and new media, such as online platforms. As a result, any communications describing goods or services on mass media may be considered advertising.

Notably, there is no definition specific to the advertising of medical devices or pharmaceuticals.

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?

All types of advertisements related to pharmaceuticals and medical devices, regardless of the medium, must be vetted and approved by the Food and Drug Department (FDD) of the Ministry of Health (MOH).

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?

Yes. The Decision on the Management of Food, Drugs, and Medical Equipment also applies to other types of products, such as 'products to enhance health' and dietary supplements used to increase dietary nutrients. However, this decision explicitly states that these products cannot be used as substitutes for drugs and are not intended to treat and cure diseases.

Additional regulations may apply depending on the age category of the products' target consumers. For instance, products for toddlers and infants in Laos are regulated by the Decree on Food Products and Equipment for Toddlers and Infants No 472 (2019), read with the Instructions on the Implementation on Food Products and Equipment for Toddlers and Infants No 1540 (2020). While the general rules regarding advertisements do not differ substantially, there are specific requirements concerning the content of advertisements for toddler and infant products, including food supplements, that must be adhered to.

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 (advertisement) in your country and if so, which ones?

There is no prohibition against pharmaceuticals and medical devices being promoted or advertised directly to the public. However, for the content to be approved, it must provide for the locations where pharmaceuticals and medical devices will be made available, and how the pharmaceuticals and medical devices will be disseminated.

The FDD has issued a list of prohibited practices regarding the advertisement of drugs and pharmaceutical products. Specifically, there is a general prohibition against advertising products that are not registered with the FDD. In this regard, prior to the marketing of drugs and/or medical devices, these products must undergo registration with the FDD. This registration process includes obtaining a local distributor licence, which is valid for a stipulated period and renewable. The purpose of this registration is to certify that the drug or medical device is deemed safe for use and consumption by people residing in Laos.

Additionally, the Decision on the Management of Food, Drugs, and Medical Equipment also outlines the following prohibitions:

- advertising drugs and medical devices through advertisements resembling lucky draws and encouraging consumers via marketing campaigns that promote drugs and medical products as prizes; and
- advertising drugs or medical products within healthcare centres or on premises that have not been duly authorised by the MOH.

In addition, the Law on Drugs and Medical Products stipulates that advertisements must be accurate, and conform with the quality of the drugs and medical products. Similarly, the Law on Consumer Protection prohibits exaggerating the characteristics of the product being advertised.

According to Article 18 of the Decision on the Management of Advertisement of Food, Drugs, and Medical Equipment, the following restrictions apply to content in advertisements for drugs in Laos:

- The advertisement must not boast about the benefits of or ingredients in the product, claiming that it can effectively relieve symptoms of disease, or prevent or treat disease. The advertisement content must not exceed the properties in the notification when applying for drug registration.
- The advertisement must not contain messages that could be construed as promoting aphrodisiacs or abortion drugs.
- The advertisement must not include endorsements or praise of the medicinal properties by consumers or other persons.
- The advertising content must not be in conflict with the traditions and culture of Laos.
- The advertising content must not persuade consumers to use drugs recklessly or unreasonably.
- The advertising content and images must be accurate and as authorised by the MOH.
- General or extensive advertising of antibiotics or prescription medication is not permitted. It is permitted to advertise these products only to persons in the medical field.

Article 19 of the decision outlines restrictions on content in advertisements for medical devices as follows:

- It must not boast or exaggerate the benefits of the product.
- It may not contain text that could be understood to promote sexual stimulants.
- It may not include an endorsement or praise of the medicinal device by consumers or other persons.
- It may not include content comparing the advertised product to other products.
- It may not include content in conflict with the traditions and culture of Laos.

According to Article 19 of the Law on Drugs and Medical Devices, it is mandatory to obtain content approval from the FDD of the MOH to advertise pharmaceutical products and medical devices through various mediums, including seminars, training, radio, television, the internet, newspapers, posters and brochures. In addition, if the advertisement is conducted via both traditional and modern media, a

Dissemination License from Ministry of Information, Culture and Tourism (MICT) is required, as stipulated in the Decision on Advertisement of Goods and Services on Mass Media, once content approval from the FDD is obtained.

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?

There is no regulation specifically governing the content of advertisements made on the internet or social media. However, the validity of the authorisation issued by the FDD for a specific advertisement may differ, depending on the medium used. In this regard, advertisements through the internet and social media are valid for a maximum period of three months. On the expiration of the three months, the advertisement authorisation must be renewed.

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)?

Yes. Promotions and/or advertisements must receive prior approval from the regulating authority prior to dissemination in the Lao marketplace. All requests must be submitted to the FDD using the specified form obtainable from the FDD. For advertisements carried out through exhibitions or seminars, it is necessary to provide the registration licence of the drug or medical product intended for the exhibition or seminar (or the notification number in the case of cosmetics), along with details regarding the content of the exhibition or seminar, information about the speaker(s), the location of the exhibition or seminar and the date.

For advertisements published in other mediums, such as newspapers, magazines and the internet, similar information will be required, as applicable, in addition to providing a sample of the advertisement to be published. For advertisements published in newspapers, magazines and so on, it is also necessary to indicate the name of the publication where the advertisement will be published. For advertisements on the internet, indicating the platform(s) where the advertisement will be published (eg, Facebook) may also be required.

According to the MOH, it takes three working days to review the application and documents provided before they issue the licence; however, in practice, it may take longer.

The duration of the validity for the licence depends on the type of medium used, as follows:

- For exhibitions and/or seminars, the validity is for the duration of the relevant exhibition or seminar, and a separate licence must be requested for each exhibition or seminar.
- For print media, such as banners, stickers, posters, brochures, books, flyers, calendars and other materials, the validity of the licence is for a period of 12 months.
- For advertisements on the internet (eg, social media), the validity of the licence is for a period of three months.

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

No. By law, it is necessary that the pharmaceuticals be registered in order to obtain authorisation for advertisements in the Lao marketplace. However, the FDD may exercise broad discretion, and it can be anticipated that, in cases of emergencies (eg, a pandemic), unregistered pharmaceuticals may be authorised for dissemination and advertisements.

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?

Generally, the Law on Consumer Protection and the Law on Business Competition prohibit advertisements that satirise or slander the goods of other operators. Accordingly, if the comparison is objective and based on facts that can be verified, the comparison is permissible, in theory. However, we are not aware of any comparison advertisements being authorised in Laos. It is understood that the FDD interprets such comparisons as denigrating the goods and products of other operators. Therefore, in practice, it is not possible to use another company's information (including brand name) as part of comparative advertisements.

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?

Article 23 of the new Law on Healthcare defines a healthcare professional (HCP) as an individual holding a healthcare practitioner licence issued by the Public Health Professionals Management Council and recorded in the database of the Public Health Professionals Management Council. In addition, according to Article 3(17), a healthcare practitioner is defined as someone possessing the knowledge and expertise necessary to practise a medical profession, such as a doctor, nurse, midwife, dentist, pharmacist and physiotherapist.

There are no specific rules applicable to advertising pharmaceuticals products and medical devices directly to HCPs. The general rules for advertising apply equally to advertisements made to both public and HCPs. Please refer to our response to Question 5 for restrictions on content in advertisements.

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?

Virtual promotional and advertising activities, including online interactions with HCPs, virtual meetings and participation in virtual congresses and symposia, may be subject to regulations outlined in the Decision on the Management of Food, Drugs, and Medical Equipment. Therefore, authorisation may be required to conduct such activities. For more detailed information, please see our responses to Questions 6 and 7.

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

As outlined in Articles 18 and 19 of the Decision on the Management of Advertisement of Food, Drugs, and Medical Equipment, endorsements by consumers and/or other persons are not permitted in advertisements for medicine and medical devices. Given that the decision specifies endorsements by other individuals, this may encompass endorsements by HCPs.

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.

There are no specific regulations on providing HCPs with samples of medicinal products or medical devices.

According to Article 3 of Regulation on Drug and Medical Product Donations No 2579/MOH, dated 12 November 2003 (the 'Regulation on Drug and Medical Product Donations'), the donation of drugs and medical products is permissible. However, prior to donating any drugs and/or medical devices to HCPs, the consent of the MOH must be sought and obtained. In addition, Article 2 of this regulation states that the donation of drugs and/or medical products is permitted for the purpose of use in healthcare treatment without charge, and must not be for commercial purposes.

It is not possible to give gifts or donations of money to HCPs. The offering of money, materials, or benefits directly or indirectly to any employee or government officials, including HCPs, falls under the definition of bribery in accordance with the Law on Public Health No 38/NA dated 18 July 2023 (the 'Law on Public Health') and the Law on Anti-Corruption.

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

The Law on Public Health and the Decision on the Use of Government Budget, Economization and Anti-Extravagant No 020, dated 25 January 2023, does not prohibit the offering of hospitality to HCPs, provided the offering is being made in connection with an event held by a national or international organisation. Examples of acceptable hospitality include meals, accommodation and travel expenses.

The offering of money, materials or benefits, directly or indirectly, to any employee or government officials, including HCPs, falls under the definition of bribery in accordance with the Law on Public Health and Law on Anti-Corruption. Such offerings are strictly prohibited.

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?

No, donations (pharmaceuticals products or funds) provided to healthcare institutions or organisations are not considered promotion activities under Lao law.

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?

Yes. There is no Lao law prohibiting pharmaceutical laboratories or medical device manufacturers or their licensees from supporting scientific or educational meetings. However, scientific or educational meetings would typically remain under the supervision of the MOH, and accordingly discussions revolving around educational or scientific topics would require the approval of the MOH.

Notably, there is no differentiation between these two sectors regarding the rules on promotion under Lao law.

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

Neither the Law on Public Health nor the new Law on Healthcare specifically addresses relationships with patient organisations. However, Article 30 of the Law on Public Health and Article 52 of the new Law on Healthcare broadly provide that the funds used in the exercise of Public Health include funds from domestic and foreign individuals, legal entities and organisations.

According to communication with officials from the MOH, in practice, companies are permitted to provide financial support to patient organisations only for purposes of professional, educational and scientific meetings, as well as to support the patient organisation's mission. To do so, the companies must submit a written proposal to the Vientiane Capital/Provincial's Public Health Department, specifying the provision of funds by the company, the nature and purpose of the support, and the particular activities being funded. In addition, the companies may also provide appropriate hospitality, such as suitable venues and refreshments or meals.

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, it is possible to engage in such activities as they are not explicitly prohibited by Lao laws. However, the advertising material for drugs and medical devices is still subject to the advertising requirements set out in the Decision on the Management of Advertisement of Food, Drugs, and Medical Equipment, as well as any regulations issued by the relevant department from the MOH from time to time. Accordingly, for compliance with legal obligations, it's prudent to establish and execute mechanisms to monitor and confirm adherence to pertinent laws. As a result, we suggest instituting an internal review and approval procedure for advertising material prior to its dissemination.

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

Yes. As HCPs are deemed government officials, they are required to declare transfers of value.

According to Article 2 of the Law on Government Officials No 74/NA, dated 18 December 2015, 'government officials' refers to Lao citizens employed to work in a state organisation, and who receive salaries and other benefits from the national budget. Therefore, HCPs working in Lao state hospitals fall under the category of government officials. As a result, they are also subject to the Decree on Declaration of Assets No 159/GOV, dated 4 June 2013, which provides that they must declare any gifts or rewards exceeding the value of LAK 5m (approximately US$240) to the state inspection body.

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?

The Decision on the Management of Food, Drugs, and Medical Equipment provides for the following sanctions:

- First violation: The violator will be subject to a warning, and the violation will be recorded in the minutes of the FDD's record.

- Second violation: The violation will be documented in the minutes recorded by the FDD and a fine of LAK 1.5m (approximately US$72) may be imposed.
- Third violation: The violation will be documented in the minutes recorded by the FDD and a fine of LAK 3m (approximately US$144) may be imposed. Additionally, the operator's business licence, along with the licence of the notification of the pharmaceuticals, may be withdrawn. This decision refers to the withdrawal of the 'notification' (which typically covers cosmetics) rather than the 'registration' (which typically covers pharmaceuticals). Furthermore, if the pharmaceutical or medical product causes adverse effects on the health of the population, additional sanctions may be applied, as deemed appropriate.

Under this decision, the FDD may also request the temporary or permanent withdrawal of the relevant advertisement.

The Law on Consumer Protection provides general sanctions for breaches of the law, stating that entities found in violation may be subject to educational measures (training on the importance of compliance with the law), fines or civil action, and penal sanctions, depending on the nature of the offence. However, no fine amounts are indicated, which may make their implementation challenging in practice.

Article 303 of the Penal Code No 118/PO dated 26 June 2017 stipulates that any person or entity denigrating advertisements of other operators or publishing advertisements promoting the characteristics of products that prove not to be true may be subject to fines from LAK 10m to LAK 20m (US$478 to US$957). The Penal Code also provides that, if such an infringement is made on a regular basis by an organised group or causes serious damages exceeding LAK 1bn (approximately US$48,000), infringers may be subject to a fine of LAK 10m to LAK 100m (approximately US$478 to US$4,785) and may be subject to imprisonment for a period of between three months to three years.

Additionally, Article 305 of the Penal Code states that any person or entity who deliberately and wrongfully advertises goods or services causing substantial damages may be sentenced to imprisonment for a period ranging from between three months to three years or re-education without deprivation of liberty. The infringer may also be subject to a percentage rate imposed on his/her salary), and/or may be fined from LAK 5m to LAK 20m (approximately US$239 to US$957).

There is no guidance on how the two overlapping articles that provide sanctions for goods causing adverse or substantial damages will apply.

The supervisory authorities actively impose penalties and other sanctions, though these can be arbitrary and negotiable. Penalties and other sanctions are not announced in a comprehensive manner.

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?

Responsibility for the enforcement of sanctions relating to pharmaceuticals generally falls under the purview of the FDD.

Violations related to unauthorised advertisements, that is, advertisements that have not been reviewed, examined and approved by the FDD, would be subject to enforcement measures. Typically, the violating advertisement will be requested to be withdrawn and a warning or fine may be imposed.

Sanctions may be more readily applied to operators with businesses in Laos and/or those who publish through mediums that are under the supervision of local authorities (eg, newspapers, social media or websites hosted in Laos), the reason being that enforcement actions against violations related to advertisements of drugs and pharmaceuticals occurring on websites or social media platforms not hosted in Laos may not be feasible for local authorities.

We have not encountered recent cases that have been subject to enforcement measures other than warnings, fines or withdrawals.

Competitors may not take direct action, but can make complaints to the relevant authorities for potential 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?
Recently, the MOH has been more active in publishing regulations pertaining to the registration of medical devices. Additionally, authorities have been working on amending the Law on Consumer Protection, which may have a significant impact on advertisements across all product types and industries. However, no tentative date for the finalisation or enforcement of the amendment has been provided. No official announcements have been made by the MOH or FDD regarding future regulations.