PROMOTION OF PHARMACEUTICALS AND MEDICAL DEVICES

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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.

Advertising generally is regulated under the Sub-Decree on the Management of Advertisements (2022), setting a range of requirements, which would also apply to advertising pharmaceuticals and medical devices.

Additionally applicable is the (Amended) Law on the Management of Pharmaceuticals (2007), which broadly governs the advertising of pharmaceuticals and medical equipment, including medical devices.

Then there are implementing regulations:

- Prakas (ministerial regulation) No 353 on the Conditions for the Promotion of Medicines, Products and Equipment for the Prevention or Treatment of Diseases (2015); and
- (Amended) Prakas No 0053 on the Conditions of Advertisements of Medicines and Preventive or Curative Products (2009).

Older regulations also cover the same subjects, but these are generally superseded by the above, more recent, regulations. If there is no conflict, the older regulations may still apply. Notably, any form of advertising of pharmaceuticals and medical devices requires prior approval from the authorities, meaning there is no self-regulatory aspect to consider.

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

The industry specific laws do not define advertising or promotion, other than stating to regulate 'all types of' promotion or advertising.

The general Sub-Decree on the Management of Advertising (2022), defines advertising in general, in Article 3:

> '*Commercial Advertising* refers to public advertising or advertising to any group of the public, in any form and by any means, in order to promote the supply of products or services or the sale or granting of real rights on real estate.'

Forms and means of advertising specified in the Sub-Decree include the following:

- advertising via audiovisual media such as TV, electronic broadcasting media (including both satellite and cable TV), and so on;
- electronic advertising, such as websites, email, electronic messages (in written, voice, or image form), ringtones, social networks, computer applications, and advertisements displayed on a phone or other smart device, or other internet-browsing software;
- print advertising such as newspapers, magazines, and bulletins;
- advertising via audio broadcasting, including radio broadcasting of any kind;
- advertising via equipment for storing any kind of audio and video, including CD, VCD, DVD, DVD, 3D/4D/5D movies, videos, or animations, and other cultural programs;
- advertising via stage performances such as concerts, art, and entertainment;
- display advertising on LCD screens, billboards, information boards, wallpaper, banners, posters, and other materials;
- advertising via discount sales, special discount sales, warehouse clearance sales, and fixed-price sales;
- advertising on the packaging of goods;
- advertising in a transportation centre or on transportation vehicles;
- advertising in a meeting, workshop, training session, or press conference;
- advertising via public display of product samples;
- advertising in educational institutions, sports centres, health institutions, religious institutions, business centres, and entertainment, banking, and industrial establishments; and

- advertising in public.

The Sub-Decree further provides that advertisement text includes any words, content, video, animations, or any other idioms intended to advertise products and services. Notably, the definition specifically refers to 'any meaning', emails in text or voice, songs and folk songs, poems, chants, comedy, ringtones, short videos, 3D/4D/5D animation, or other idioms intended to advertise the supply of products and services.

There is no clear difference made between promotion and advertising under any of the regulations.

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?

The Ministry of Health (MoH), and specifically its Department of Drugs & Food (DDF), regulates the sector.

The MoH has inspection powers, but in practice they take limited enforcement action, other than issuing notices on non-compliant advertising, and in rare instances they revoke company licences or product registrations.

Additionally, the Ministry of Information has the power to order media outlets to remove non-compliant advertising of pharmaceuticals and medical devices, under Joint Prakas (an interministerial regulation) No 75/063 MBrK and No 007 RNS/MP.

A recent development is that the Sub-Decree on the Management of Advertising (2022) also permits the consumer protection authority (in full, the Consumer Protection, Competition, and Fraud Repression Directorate-General (CCF)) to action against non-compliant advertising of any type of product, including pharmaceuticals and medical devices.

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

Other product categories fall under the same regulations, according to the interpretation of the health authorities.

Any products and equipment (including devices) that are used for the prevention or treatment of diseases falls under Prakas No 353 on the Conditions for the Promotion of Medicines, Products and Equipment for the Prevention or Treatment of Diseases (2015), and (Amended) Prakas No 0053 on the Conditions of Advertisements of Medicines and Preventive or Curative Products (2009).

For example, health supplements or external health supporting products are therefore regulated under the same regulations. There are no regulated special considerations. In practice, we note the regulations are applied more loosely to these categories, when compared to pharmaceuticals and medical devices.

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?

Prescription drugs may not be advertised in Cambodia, according to Joint Prakas (an interministerial regulation) No 75/063 MBrK and No 007 RNS/MP, Article 2, and the (Amended) Prakas No 0053 on the Conditions of Advertisements of Medicines and Preventive or Curative Products (2009), articles 4–6.

Furthermore, the same regulations prohibit the public advertising of pharmaceuticals containing dangerous substances, and the following types of pharmaceuticals:

- addictives;
- psychotropics;
- to treat abortion;
- to treat STDs/STIs;
- to treat HIV/AIDS;
- to treat cancer;

- sexual-stimulating drugs; and
- those for infants.

We note that advertising that is not to the general public, but directly aimed at healthcare professionals, may include the prohibited types of products and prescription products – as long as the advertising has received prior approval from the authorities, and the means of advertising is limited under the regulations to workshops, medical bulletins, medical brochures, and through giveaways (stationery and the like) for healthcare professionals.

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?

This type of advertising is regulated as any other form of advertising. There are no specific regulations applicable when advertising pharmaceuticals and medical devices through the internet and social media.

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, prior approval of the advertisement is mandatory.

The applicant must submit an approval request letter to the authorities, and attach the following:

- product registration certificate;
- draft of the advertisement (script, photos, DVDs or other as appropriate); and
- samples of the advertised product.

The applicant must agree to sign the approval agreement between the authority and the advertiser, which has basic conditions, such as to maintain the related product registration, the advertiser will not use prohibited means of advertising, that the timeframe for advertising will be respected, and similar basic conditions. This is a standard format agreement.

The authorities take 30 days to issue their approval after a full submission. Depending on the type of advertisement, the advertiser may receive a six-to-12-month approval validity period. The approval may be renewed indefinitely.

Prohibited means

Under the (Amended) Prakas No 0053 on the Conditions of Advertisements of Medicines and Preventive or Curative Products (2009), pharmaceuticals and medical devices may not be advertised using the following means:

- at cinemas, theatres, and open markets;
- near public transport;
- printed on T-shirts, raincoats, umbrellas or hats;
- on street side billboards other than those approved by the MoH;
- at or around concerts or other public performances;
- near pharmacy signs, or using a pharmacy logo;
- inside, or near, clinics or other health institutions, or using their logo;
- by using artists, famous presenters, or other well-known people, unless with MOH approval.

Any type of advertising may not use wording that discusses the potential advantages to health or other wording related to the quality of the product, in a manner that exaggerates or misleads. This latter prohibition is a key requirement throughout all regulations on advertising of pharmaceuticals and medical devices.

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

No, only authorised pharmaceuticals can obtain advertising approval.

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?

Comparable advertising is prohibited generally in advertising under the Sub-Decree on the Management of Advertising (2022), if done with 'the intention of degrading or affecting the products and services of others'.

This 2002 Sub-Decree is rather new, so the scope of this prohibition has not yet been put to the test. There is rarely any comparative advertising in Cambodia, in our experience.

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?

The Law on the Regulation of Healthcare Practitioners regulates healthcare professionals. Article 4 of the law provides the following definitions:

> '*Health Professional* refers to a physician, dentist, midwife, nurse, pharmacist, laboratory specialist, physical therapist, dental specialist, radiologist, and other health professional who is registered with relevant Health Professional Council.
> *Health Practitioner* refers to a health professional who holds a health practitioner license.'

Please be reminded that prior approval for all types of advertising is needed, including advertising to health practitioners.

Advertising to health practitioners may include content that is prohibited when advertising to the public. The permitted content includes advertising of the following:

- prescription products;
- pharmaceuticals containing dangerous substances;
- addictive drugs;
- psychotropics;
- pharmaceuticals to induce abortion;
- pharmaceuticals to treat STDs/STIs;
- pharmaceuticals to treat HIV/AIDS;
- pharmaceuticals to treat cancer;
- sexual-stimulating drugs; and
- pharmaceuticals for infants.

In the case of the above products being advertised to health practitioners, the possible means of advertising are restricted, namely to workshops, medical bulletins, medical brochures, and through giveaways (stationery and the like).

Generally, the key requirement to meet is to ensure that the advertising (including when made directly to health practitioners) may not use wording that discusses the potential advantages to health or other wording related to the quality of the product, in a manner that exaggerates or misleads.

Companies should also take into consideration anti-corruption laws when engaging with healthcare practitioners, when the activity has a commercial nature, although this generally does not pose restrictions on content per se.

Additionally, healthcare practitioners partaking in these types of activities should ensure that their participation does not violate their Code of Ethics. The Code of Ethics may apply to those participating, and those providing the information, such as presenting at workshops.

Under articles 5 and 18 of the Code of Ethics, the practitioners participating must:

- remain independent; and
- not benefit in their personal financial situation.

Under articles 13 and 14, those providing information must:

- speak carefully and consider the repercussion of their words towards their public;
- only mention data that has been confirmed and validated;
- avoid publicising for their personal benefit, the organisations they are working with or supporting or for any other reason than the public interest; and
- not publicly speak regarding any diagnosis or treatment that is not validated, and without linking it to prepared (scientifically supported) information.

We believe it is vital to take these restrictions into account when planning advertising activities.

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 this. The regular advertising rules apply to these types of activities.

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?

The Code of Ethics applies to those providing the information for an advertising activity, such as presenting at workshop, or endorsements.

Under articles 5 and 18 of the Code of Ethics, the practitioners must:

- remain independent; and
- not benefit in their personal financial situation.

Under articles 13 and 14, those providing information must:

- speak carefully and consider the repercussion of their words towards their public;
- only mention data that has been confirmed and validated;
- avoid publicising for their personal benefit, the organisations they are working with or supporting or for any other reason than the public interest; and
- not publicly speak regarding any diagnosis or treatment that is not validated, and without linking it to prepared (scientifically supported) information.

Endorsements therefore appear difficult to do in full compliance – the professional who is endorsing a product will likely be seen as benefiting in case there is any payment made or benefit provided for the endorsement.

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.

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- psychotropics;
- pharmaceuticals to induce abortion;
- pharmaceuticals to treat STDs/STIs;
- pharmaceuticals to treat HIV/AIDS;
- pharmaceuticals to treat cancer;
- sexual-stimulating drugs; and
- pharmaceuticals for infants.

In the case of the above products being advertised to health practitioners, the possible means of advertising are restricted, namely to workshops, medical bulletins, medical brochures, and through giveaways (stationery and the like). Samples are therefore not allowed.

In the case of advertising other types of pharmaceuticals or devices, there is no clear prohibition on providing samples. However, as prior approval is required, the authorities may not allow providing a sample. In practice, samples are rarely approved for advertising purposes.

Gifts or donations of money are not explicitly prohibited, but will almost certainly violate the Code of Ethics as doctors may not receive any benefits, and therefore this approach to advertising will not receive authorisation, in our opinion.

Anti-corruption laws should be considered as well in the case of gift-giving or donations of money. Cambodian law prohibits providing gifts or other benefits of any value to any employee or public official to

induce that person to perform or abstain from performing his or her duty. Cambodian law does not provide a value under which a gift or other benefit is presumed lawful.

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

Offering hospitality is not prohibited, but as a form of advertising it would require prior approval. The authorities may deem this approach as a benefit for the health professional, that it is not permitted to receive under the Code of Ethics, or it may decline authorisation as it may potentially lead to corruption of the professional.

Cambodian law prohibits providing gifts or other benefits, including hospitality, of any value to any employee or public official to induce that person to perform or abstain from performing his or her duty. Cambodian law does not provide a value under which a gift or other benefit is presumed lawful.

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?

A donation is permitted. However, when provided by an authorisation holder, a donation may be seen as commercial in nature, especially if the receiver of the donations purchases products from the giver of the donation. In short, given the broadly defined laws on advertising and on anti-corruption, we deem it difficult to argue there is no commercial aspect whatsoever to a donation to a buyer of the products of the giver.

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?

If the meetings are purely scientific or educational, they are not subject to any approval under Cambodian law. To avoid the activities being qualified as a form of health product advertising, such activities should be limited to being purely educational, without any commercial aspects.

In case there is a commercial aspect to activities, prior advertising approval is required. In that case, the authorities will need to review all materials and content related to the activities, and issue approval before the advertising activities may take place.

We would like to highlight here that the authorities have considered a healthcare company providing branded logbooks, agendas, pens, or other similar branded gimmicks, as advertising materials triggering the pre-approval requirement.

Discussing products currently marketed in Cambodia, or those to be launched on the market in the future, will likely be seen as advertising. If the products discussed are being marketed in Cambodia and the product owner is funding the activities, we expect that the authorities will see the intended activities as health product advertising.

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

We understand that these types of organisations do not exist yet in Cambodia, and are not yet regulated specifically.

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?

We understand that the entity requesting approval for advertising must be either the Marketing Authorisation (MA) holder, or the appointed distributor of the MA holder. Third parties may be executing the activities (media companies, for example), but the legal responsibility lies with the holder of the advertising approval.

There are no set conditions for a third party executing an advertising activity.

Co-promotion is possible, but one of the parties will need to obtain the advertising approval and will hold the legal responsibility for the advertising activities.

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

This is not made mandatory.

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?

In practice, the authorities will issue notices and warnings against advertisements that are non-compliant, allowing the advertiser to make amendments. In case unregistered products are advertised, no amendments are allowed, and all advertising must cease immediately upon notice or warning.

If the notices are ignored, or the advertisement violation poses a great health risk, product recalls can be ordered, as well as enforcement authorities actively seizing products found in the market. A product registration may be revoked, in case of non-compliance that leads to a health risk.

Lastly, a ministerial order can be made to stop running the advertisements, and the media running the advertisements must abide by the order as well.

In terms of potential legal penalties, a monetary fine from KHR 1,000,000 (approximately US$250) to KHR 10,000,000 (approximately US$2,500) may apply, in addition to the possibility of suspending the business licence of the advertising entity, for one month to three months. Repeat offenders may have these punishments doubled. These are industry specific penalties, from the (Amended) Law on the Management of Pharmaceuticals (2007).

The recent Sub-Decree on Advertising provides additional potential penalties for violating the general advertising rule. Advertising that violates the general rules which may lead to administrative fines, ranging between KHR 10–50m (approximately US$2,500–12,500). In cases where aggravating circumstances apply, for example due to physical harm or even death resulting from the non-compliant advertising, prison sentences apply, from three months up to even five years.

Additionally, violating the rules may lead to the following administrative sanctions:

- written warning;
- suspension, revocation, or cancellation of advertising licences; or
- suspension, revocation, or cancellation of a certificate of business registration, licence or permit of business-services.

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?

The MoH, and specifically its DDF, regulates the sector and is responsible for enforcement.

They have inspection powers, but in practice they take limited enforcement action, other than issuing notices on non-compliant advertising, and in rare instances they revoke company licences or product registrations.

Additionally, the Ministry of Information has the power to order media outlets to remove non-compliant advertising of pharmaceuticals and medical devices, under Joint Prakas (an interministerial regulation) No 75/063 MBrK and No 007 RNS/MP.

A recent development is that the Sub-Decree on the Management of Advertising (2022) also permits the consumer protection authority (CCF) to action against non-compliant advertising of any type of product, including pharmaceuticals and medical devices.

Enforcement is not (yet) very strict, unless it poses a health risk. However, enforcement efforts have been rising over the past year.

We have not yet seen competitor claims coming to fruition – we note that recently more interest has peaked in this area from the industry, as enforcement is on the rise, but non-compliance is still prevalent, causing an uneven playing field.

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?

General product labelling, and especially using local language, has been a major development over the past few years. We expect that in the health product industry this requirement will be more strictly enforced in the coming year.

Business to health professional advertising has been popular, but we see many companies violating the rules. We have seen the MoH become increasingly stricter on prior approvals, but not yet on enforcement. We expect this to change in the coming years.