



Interacting with  
Healthcare  
Professionals in Asia  
Pacific

2020

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## Foreword

Healthcare companies face a variety of complexities in doing business in Asia Pacific. For instance, establishing ethical relationships with healthcare professionals is a critical part of developing and marketing products and often face legal sanctions, cultural blunders and multifaceted standards.

In an effort to help clients navigate opportunities and challenges in the industry, Baker McKenzie developed the ***Interacting with Healthcare Professionals Guide***. In this updated 2020 edition, you will learn more about the regulations and traditional practices governing interactions with healthcare professionals across the region. Particularly, we discuss legislations relevant to the following:

- *Can a pharmaceutical company provide gifts to a healthcare professional?*
- *Is there “transparency legislation” relating to payments by pharmaceutical companies to healthcare professionals?*
- *Can a pharmaceutical company offer giveaways or other gimmicks to a healthcare professional? Is there a specific threshold regulated by law?*
- *Can a pharmaceutical company sign a service contract (such as for speaking and chairing at meetings, translating medical documents, writing medical articles and/or giving medical training) with a healthcare professional?*
- *Are healthcare professionals required by law to obtain written pre-approval from their employers to be able to attend an event organized by a pharmaceutical company?*

We hope you find this material useful and pertinent. We would be happy to answer your questions. For inquiries, please e-mail me or the partners responsible for each chapter. You will find their contact information at the end of this handbook.



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# Australia





## Australia

Elisabeth White, Sabrina Chan and Amy Middlebrook

### 1. Can a pharmaceutical company provide gifts to a HCP?

In Australia, there is no express legal prohibition on the provision of gifts to HCPs by pharmaceutical companies.

However, the Medicines Australia Code of Conduct (“**MA Code**”) sets out standards of conduct for the activities of companies when engaged in the promotion of prescription products.

Member companies of Medicines Australia are obliged to comply with the MA Code. All pharmaceutical industry participants are encouraged to follow the MA Code as representative of industry best practice; and the Therapeutic Goods Administration (“**TGA**”) requires, as a condition of product registration, that sponsors comply with the MA Code when promoting or advertising prescription medicines.

The MA Code prescribes that no gifts, benefits in-kind or pecuniary advantage should be offered or given to HCPs as an inducement to recommend, prescribe, dispense or administer a pharmaceutical company’s product (e.g., gift vouchers, tickets to sporting events, cash or cash equivalents).

There are limited exceptions for (a) company-branded items of stationery; (b) educational material directed to HCPs or patients; (c) sponsorship to attend an educational event; and (d) hospitality at an educational event.

The Code of Practice of the Medical Technology Association of Australia (“**MTAA Code**”) adopts a substantively similar position. The MTAA Code is compulsory for members of the MTAA and, as an industry code, represents best practice for all companies in the medical technology industry.

## 2. Is there “transparency legislation” relating to payments by pharmaceutical companies to HCPs?

There is no specific “transparency of payment to healthcare professionals” legislation in Australia. In Australia, the extent to which such payments need to be disclosed by pharmaceutical companies is a matter for self-regulation by the industry in accordance with voluntary industry codes, including the MA Code.

Since 1 October 2016, the MA Code requires companies in the prescription medicines industry to report the following transfers of value provided to each HCP:

- Fees paid for speaking at an educational meeting or event.
- Sponsorship to attend an educational event (including any airfare, accommodation or registration fees directly associated with the meeting (whether held within or outside Australia)).
- Fees paid to HCP consultants in Australia or to their employers on their behalf for services (including consulting fees, accommodation and airfares (both within and outside Australia) associated with the provision of the consulting services). However, this does not include payments to consultants in relation to research and development work, including the conduct of clinical trials.
- Fees paid to HCP advisory board members (including all payments in respect to advisory board sitting fees, accommodation and airfares (both within and outside Australia) associated with the activities of the advisory board).
- Fees paid for the purpose of market research.

Where a HCP requests a monetary payment be made to a third party, such a payment must still be disclosed by reference to the individual

HCP. However, the report will identify that that payment was made to a third party.

Such transparency data must be published on the website of the pharmaceutical company for at least three years. This requirement is mandated by the Australian Competition and Consumer Commission as a condition of its authorization of the MA Code.

The MTAA Code does not include equivalent transparency reporting provisions.

Australia also has anti-bribery legislation with local and potentially extraterritorial effect. The legislation is relevant to dealings with individuals who may be public officials (foreign or local). For example, it is an offense under Division 142 of the Criminal Code Act 1995 (Cth) to:

- Dishonestly provide, offer, or promise, directly or indirectly, a benefit (which is defined broadly to include “any advantage and is not limited to property”) to another person.
- If the receipt or expectation of receipt of the benefit would tend to influence a Commonwealth public official in the exercise of his or her duties.

While there is limited guidance on the application of this provision, the definition of a “Commonwealth public official” is broad and in the healthcare context may include a healthcare professional working in a public hospital.

It is a criminal offense under the Crimes Act 1900 (NSW) for any person to corruptly give, or offer to give, to any agent (or to any other person with the consent or at the request of any agent) any benefit (a) as an inducement or reward for the agent’s doing or not doing something in relation to the affairs or business of the agent’s principal; or (b) the receipt or expectation of which would in any way tend to influence the agent to show favor to any person in relation to the

affairs or business of the agent's principal. There are corresponding or similar provisions in the crimes acts/criminal codes of other states in Australia.

### 3. Can a pharmaceutical company offer giveaways or other gimmicks to a HCP? Is there a specific threshold regulated by law?

The only types of giveaways that may be accepted in certain limited circumstances are company-branded and educational items directly related to the practice of medicine.

Company-branded pens, notepads and/or educational material may be given to delegates attending a company educational event and/or a sponsored educational event and/or at trade displays.

Items of an educational nature must be dedicated to improving the quality use of medicines and/or assisting a patient in their understanding of a condition or disease.

Meals and beverages at educational events must be secondary to the educational content and within Australia must not exceed AUD 120 (excluding GST and gratuities). Travel and accommodation must only be provided if justified. Entertainment must not be provided.

In certain circumstances, pharmaceutical companies may sponsor a HCP to attend an educational event directly related to the HCP's area of expertise.

Competitions for HCPs that include the provision of a prize are not permitted. Companies may offer a quiz for HCPs at a trade display, but no prize may be offered.

No gift, benefit in kind or pecuniary advantage shall be offered or given to HCPs as an inducement to recommend, prescribe, dispense or administer a member company's product(s).

#### 4. Can a pharmaceutical company sign a service contract (such as for speaking and chairing at meetings, translating medical documents, writing medical articles and/or giving medical training) with a HCP?

Yes, a pharmaceutical company may enter into a service contract with one or more HCPs to provide services, advice and/or guidance on a range of matters. A legitimate need must be clearly identified, while the purpose and objective of the interaction must be clearly articulated in a written contract. Any remuneration provided must be commensurate with the work involved and should reflect fair market value. A company may provide reasonable travel, accommodation or hospitality to consultants in association with consulting services. Interactions between companies and consultants must not include entertainment.

In the private sector, whether or not prior approval from an employer is required will depend on the contract of employment between the HCP and his/her employer.

If the HCP is a public sector employee, each Australian state will have differing laws, with consent likely to be required.

#### 5. Are HCPs required by law to obtain written pre-approval from their employers to be able to attend an event organized by a pharmaceutical company?

There is no legal requirement; however, employers of HCPs are likely to have their own policies and procedures governing permissible attendance at events organized by pharmaceutical companies.



# Cambodia



## Cambodia

Simon Burlinson

For the purposes of responding to the specific questions enumerated below, we have considered all Cambodian legislation we consider appropriate, including, but not limited to, the following:

- Law on the Amendment to the Anti-Corruption Law dated 1 August 2011
- Law on Anti-Corruption dated 17 April 2010 (together with the Law on the Amendment to the Anti- Corruption Law dated 1 August 2011 ("Cambodian Anti-Corruption Laws"))
- Criminal Code of Cambodia dated 30 November 2009 ("Criminal Code")
- Law on the Amendment to the Law on Pharmaceuticals Management dated 28 December 2007 Law on the Management of Private Medical, Paramedical and Medical Aid Professions dated 22 November 2000
- Law on Pharmaceutical Management dated 17 June 1996
- Sub-Decree No. 61 ANKr. BK of the Royal Government dated 28 August 2003 on Physicians' Code of Ethics for Doctors ("Code")
- Our inquiries at the Ministry of Health

### 1. Can a pharmaceutical company provide gifts to a HCP?

#### HCP in the private sector

Currently, there is no specific law that prohibits a pharmaceutical company from providing gifts to a HCP working in the private sector.



However, Article 93 of the Physicians' Code of Ethics for Doctors prohibits all paid HCPs, working in both the public and private sector, from accepting any cash award or gift that influences their independence and quality of service. In Cambodia, many HCPs work both for the government and in their own clinics.

## HCP in the public sector

Under Cambodian Anti-Corruption Laws (Articles 4 and 32) and the Criminal Code (Articles 594 et seq.), the granting of gifts, offers, promises or interests, whether direct or indirect, to a public official with the purpose of influencing them to perform or refrain from performing an act related to or facilitated by their function shall be regarded as bribery unless the gift is considered to be customary such as at a wedding. Therefore, a gift granted by a pharmaceutical company to a HCP is regarded as bribery if the HCP is a civil servant serving public functions and the purpose of doing so is to influence their duties. Criminal liability applies to breach of the relevant provisions.

## 2. Is there transparency legislation relating to payments by pharmaceutical companies to HCPs?

No, subject to the response provided in question 4 relating to service contracts. There is currently no specific Cambodian law requiring the disclosure of payments made by pharmaceutical companies to HCPs, either by the companies themselves or the HCPs. However, sound corporate compliance should be maintained and we recommend that pharmaceutical companies detail and record all payments made to HCPs in the event that the relevant ministries question any allegation of impropriety or bribery.

### 3. Can a pharmaceutical company offer giveaways or other gimmicks to a HCP? Is there a specific threshold regulated by law?

There are no laws restricting a pharmaceutical company from offering giveaways to a HCP subject to their not being considered as influencing the HCP's independence and quality of service (as mentioned above). However, in practice and in Cambodian culture (as is generally the case for drug representatives in other jurisdictions), giveaways provided by a pharmaceutical company are normally items similar to stationery, T- shirts, notebooks, pens, calendars, bags, educational brochures, etc. Pharmaceutical companies are not encouraged to offer high-priced giveaways that may influence the HCP's purchasing power and cause them to disregard a drug's quality. There is no legally defined threshold.

### 4. Can a pharmaceutical company sign a service contract (such as for speaking and chairing at meetings, translating medical documents, writing medical articles and/or giving medical training) with a HCP?

Under Cambodian law, HCPs are permitted to engage in other professional activities outside of their normal practice, provided that the other work does not conflict with their freedom, dignity and professionalism (see Article 24 of the Code). They shall not use this additional work to gain personal advantage from their medical advice and prescriptions issued (see Article 23 of the Code). Article 88 of the Code prohibits a HCP from entering into a service contract in return for gifts that influence their impartial decision making or service quality. The service contract should be created based on the independence of the medical professional principle and be sent to the Provincial/Municipal Medical Council for verification (see Article 87 of the Physicians' Code of Ethics for Doctors). Article 19 of the Code

requires the HCP not to tolerate any public or private organization, where they are working or cooperating with, in using their name or their profession for commercial purposes. Moreover, Article 22 of the Code also prohibits the creation of a relationship between a HCP and another HCP, a pharmacist, a medical assistant or the public, whether physically or mentally, to provide advantages to an individual.

Regardless of the restriction, all HCPs are encouraged by the Code to be involved in all public interest activities, including implementation of service contracts. During performance of these services, such as providing public speeches on healthcare education, they must take due care not to promote any personal interest. They should only raise information that is well founded and should not propagandize for personal interest or the interests of an organization they are working with (see Article 13 of the Code).

## 5. Are HCPs required by law to obtain written pre-approval from their employers to be able to attend an event organized by a pharmaceutical company?

There is no law that requires HCPs to obtain prior approval from their employer; however, their employment contract may prescribe such a condition. All government officials must get permission. Companies may pay to have government officials attend events, but the companies must not pay the government official per diem on top of that. The event must be related to the HCP's work.

It should be noted that stricter provisions are being considered and may be adopted in the future. However, no laws or regulations under consideration have been passed to date since 2015.

# China



## China

Clement Ngai and Vivian Wu

### 1. Can a pharmaceutical company provide gifts to a HCP?

PRC laws prohibit bribery offered by a pharmaceutical company to a HCP in exchange for improper benefits. Such “bribery” can be in the form of cash, gift, property, things of value, entertainment, hospitality and travel, among others.

- The key factor to determine if a gift is considered a bribe is whether or not the provision of the gift is intended to affect the HCP’s impartial performance of his/her duties.
- If the value of the bribe is over RMB 100,000 (approximately USD 14,170<sup>1</sup>) and other aggregating factors (e.g., offering bribes to multiple recipients), the pharmaceutical company and its responsible managing person may be held criminally liable. This threshold can be calculated accumulatively. For example, if the company provided bribes to various HCPs in different healthcare institutions over the past three years, and the total value of bribes given is over RMB 100,000, it can still be subject to criminal liability.
- If the bribe is given for the purpose of influencing the sales of certain products, such activities may also be investigated and covered by administrative penalties by the local administration for market regulation even though the gift value does not meet the criminal prosecution threshold.

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<sup>1</sup> Based on the exchange rate published by the PRC State Administration of Foreign Exchange on 23 August 2019, the exchange rate between USD and RMB is 7.0572.

- A bona fide courtesy gift with modest value may be allowed. However, it is generally recommended that the gift value be limited to RMB 200 (approximately USD 28.3<sup>2</sup>). According to certain rules issued in the 1990s, Chinese government officials are required to turn over gifts over the value of RMB 200 (approximately USD 28.3). In practice, many multinational companies (MNCs), in particular in high-risk sectors such as healthcare industry, tend to use the RMB 200 value as the limit for gifts.

Despite the above, if the pharmaceutical company is a member of the China Association of Enterprises with Foreign Investment R&D-Based Pharmaceutical Association Committee (RDPAC), the company should also comply with the RDPAC Code, i.e., the RDPAC Code of Practice (2015 Revision) (“**RDPAC Code**”).

According to the main text of the RDPAC Code:

- A pharmaceutical company is prohibited from providing cash or cash equivalents to HCPs.
- Gifts for the personal benefit of HCPs are prohibited, such as sporting or entertainment tickets, electronic items, etc.
- Promotional aids of minimal value and quantity may be provided or offered to HCPs if relevant to the practice of the HCPs.
- Items of medical utility may be offered or given free of charge occasionally, on the condition that such items are of modest value, do not offset routine business practices, and are beneficial to enhancing the provision of medical services and patient care.

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<sup>2</sup> For the purpose of this section, we have applied the exchange rate published by the PRC State Administration of Foreign Exchange on 23 August 2019, which is USD 1 = RMB 7.0572.

## 2. Is there “transparency legislation” relating to payments by pharmaceutical companies to HCPs?

In China, there is no specific “transparency legislation” relating to payments by pharmaceutical companies to HCPs. However, several regulations issued by Chinese regulators intend to promote the transparency of payments to HCPs or other parties in the healthcare sector, for example:

- “Several Provisions Regarding the Anti-Unfair Competition in the Healthcare Industry” issued by the then State Food and Drug Administration and effective from 1 December 1993, provide that drug manufacturers can provide discount to the counterparty in an open manner. The discount should be recorded truthfully and accurately in the books. “Off-the-book” kickbacks should be regarded as bribes and be strictly prohibited.
- “Nine Prohibitions to Strengthen Ethical Conduct in the Healthcare Industry” issued by the
- People’s Republic of China’s National Health and Family Planning Commission (NHFPC) on 26 December 2013 prohibit HCPs from accepting kickbacks from enterprises or individuals.
- “Guiding Opinions of the General Office of the State Council on Improving the Centralized Drug Procurement for Public Hospitals” issued by the State Council on 9 February 2015 emphasize the transparency requirements during the drug procurement process.
- “Administrative Measures on Accepting Donations for Public Welfare by Healthcare Institutions (for Trial Implementation)” issued by the NHFPC and effective from 26 August 2015 require healthcare institutions (e.g., hospitals) to publish their policies and procedures on accepting donations, as well as details of the

donations (e.g., property for donation, utilization of donation, audit reports and evaluation results of the donation project). The NHFPC and its local counterparts are encouraged to set up a unified information-sharing platform to publish information on donations.

**3. Can a pharmaceutical company offer giveaways or other gimmicks to a HCP? Is there a specific threshold regulated by law?**

Such giveaways may be considered gifts as discussed above.

A bona fide souvenir is allowed. However, the gift value should normally be no more than RMB 200 (approximately USD 28.3). It is also suggested that the company logo or event name be painted on the souvenir.

**4. Can a pharmaceutical company sign a service contract (such as for speaking and chairing at meetings, translating medical documents, writing medical articles and/or giving medical training) with a HCP?**

Under PRC law, a pharmaceutical company may sign a service contract with a HCP. However, it is recommended that pharmaceutical companies ensure that the HCP's employer has approved the service contract, which can be used as prima facie evidence that the execution and performance of the service contract by the HCP does not violate the internal rules of the HCP's employer.

In addition, PRC law strictly prohibits HCPs from participating in promotions for medical, food, healthcare products, etc., or disclosing patients' or customers' personal data and medical information. Separately, HCPs may not collate prescription statistics for



commercial purposes or provide support for statistics of medical marketing personnel.

Moreover, according to the RDPAC Code, a pharmaceutical company may sign a service contract with a HCP if the contract is not signed in exchange for prescribing, recommending, purchasing, supplying or administering products, or for a commitment to continue to do so. The service contract shall not be signed in a manner or on conditions that may have an inappropriate influence on the HCP's prescribing practice. The criteria for selecting the service providers must be directly related to the identified need and the service providers must have the expertise necessary to provide the service. The number of service providers must not be greater than the number reasonably necessary to achieve the identified need. Compensation for the services must be reasonable and reflect the fair market value of the services provided.

## 5. Are HCPs required by law to obtain written pre-approval from their employers to be able to attend an event organized by a pharmaceutical company?

There is no statutory requirement under PRC law that a HCP must obtain written pre-approval from his/her employer to attend an event organized by a pharmaceutical company.

However, it is advisable for the pharmaceutical company to formally address the invitation to the HCP's employer and maintain a record of documents showing that the HCP's employer has approved the HCP to attend the pharmaceutical company's educational event.

If a pharmaceutical company provides sponsorship (e.g., registration fees and travel expenditures) for HCPs to attend an educational event, it is possible that such sponsorship could be viewed as a donation or grant under PRC law. In such case, the pharmaceutical company should sign a contract with the employer of the HCP to

ensure that the sponsorship is provided to the healthcare institutions instead of the HCP individual. Further, it should avoid designating the specific beneficiary (i.e., which HCP attended the event) for the donation.

# Hong Kong



## Hong Kong

Isabella Liu, Mini vandePol, Roberta Chan and Tracy Wut

### 1. Can a pharmaceutical company provide gifts to a HCP?

The Prevention of Bribery Ordinance (PBO) prohibits the unlawful offering, soliciting or acceptance of an “advantage” (which includes gifts under its legal definition) to or by (a) a government employee/official or public servant, or (b) any person acting as an agent of another person (which would cover doctors in private hospitals). HCPs in both the public and private sectors are therefore covered by the PBO. HCPs employed by government hospitals managed by the Hospital Authority are public servants who must comply with the relevant provisions of the PBO, in particular sections 4 and 5, which govern the public sector. Those sections are aimed at preventing public servants from abusing official authority for private gain and safeguarding the interests of public bodies and the community at large; and maintaining fair play in the procurement of contracts with public bodies. Similarly, HCPs in private practice are required to observe section 9 of the PBO. Generally speaking, whether an offering or acceptance of an advantage is lawful in Hong Kong depends on whether or not permission or lawful authority is provided.

It is also a general principle under the Hong Kong Association of Pharmaceutical Industry’s (HKAPI) Code of Practice, 19th Edition, 2019 (**Code**, a local industry association code to which compliance by non-members is voluntary) that no financial benefit or benefit-in-kind may be provided or offered to a HCP in exchange for prescribing, recommending, purchasing, supplying or administering products or for a commitment to continue to do so.

Under the Code, inappropriate financial, material or personal benefits (including festive gifts), gratuitous payments in cash or cash

equivalents should not be offered to HCPs to influence them in the prescription of products. Promotional items of nominal value, provided free of charge and on an infrequent basis, are only permissible for the promotion of over-the-counter drugs and if they are related to the HCP's work and/or entail a benefit to patients.

## 2. Is there “transparency legislation” relating to payments by pharmaceutical companies to HCPs?

There is no specific “transparency of payment to healthcare professionals” legislation in Hong Kong.

The PBO prohibits unlawful offering and acceptance of an advantage by HCPs working in both private and public hospitals. Prior consent by the recipient's employer/organization generally makes such offering and acceptance lawful.

Doctors are subject to the Medical Council of Hong Kong's Code of Professional Conduct and the Hong Kong Hospital Authority issues additional internal guidelines for HCPs in public hospitals. The HKAPI's Code provides industry guidelines on payment or donation to HCPs.

## 3. Can a pharmaceutical company offer giveaways or other gimmicks to a HCP? Is there a specific threshold regulated by law?

Giveaways may fall under the wide definition of “advantages” under the PBO (see above discussion on gifts). Under the Code, the following are generally allowed:

- Promotional materials (containing mandatory information on products)

- Entertainment of a modest nature by reasonable local standards and which is incidental to refreshments and/or meals
  - Promotional items of nominal value (HKD 150 or USD 20 per item), provided free of charge and on infrequent basis, are only permissible for the promotion of over-the-counter drugs and if they are related to the HCP's work and/or entail a benefit to patients
4. Can a pharmaceutical company sign a service contract (such as for speaking and chairing at meetings, translating medical documents, writing medical articles and/or giving medical training) with a HCP?

There is no specific prohibition against a pharmaceutical company signing a service contract with HCPs. However, the PBO should be observed since a service contract may be considered an “advantage” under the PBO. Due authorization from the employer/principal should be acquired to minimize the risk of violating the PBO.

- For HCPs in the public sector, such a contract will require prior approval by the public hospital. Also, a pharmaceutical company may not be able to enter into a contract with a specific HCP unless the HCP is contracting in their own capacity.
- For HCPs in the private sector, it would be subject to the arrangement between the HCP and their employer.

5. Are HCPs required by law to obtain written pre-approval from their employers to be able to attend an event organized by a pharmaceutical company?

There are no specific requirements under applicable laws and regulations in Hong Kong. Whether or not authorization is required depends on the HCP's employer. For public hospitals, authorization is required under the Hospital Authority's internal guidelines. Also, designation of specific HCPs for event attendance is generally not recommended.

# Indonesia





## Indonesia

Cahyani Endahayu and Reagen Lodeweyjke Mokodompit

### 1. Can a pharmaceutical company provide gifts to a HCP?

Generally, pharmaceutical companies are prohibited from giving valuables to healthcare professionals (“HCPs”), unless it is structured as a sponsorship.

#### ***Prohibition on Provision of Gifts to HCP***

The reasons are as follows:

- (a) Pharmaceutical companies and/or wholesalers are strictly prohibited from (i) providing any bonus or gifts to, or (ii) entering into any cooperation with, any HCP that has the authority to prescribe drugs. This is regulated under Article 9 of the Head of Drugs and Food Monitoring Body (*Badan Pengawas Obat dan Makanan* or **BPOM**) Decision No. HK.00.05.3.02706 on Promotion of Drugs (“**BPOM Decision 05**”).
- (b) HCPs must comply with the code of ethics relevant to their profession. In most cases, the code of ethics will specifically say that they cannot receive gifts of any kind that would cause them to have a conflict of interest in their professional work.
- (c) Additionally, most HCPs in practice have the status of state official and we usually advise our clients to avoid performing any transfers of value to a HCP with state-official status. This is due to the high risk that such action could be considered a ‘gratification’ (which is subject to a criminal sanction). Gratification and bribery are regulated under Law No. 31 of 1999 on Eradication of Corruption Act as amended by Law No. 20 of 2001 (“**Anti-Corruption Law**”). Based on the elucidation of Article 12 B of the Anti-Corruption Law, gratification is defined as

any kind of gifts to a state official in a broad sense, which includes gifts in the form of money, goods, discount, commission, no-interest loans, transportation tickets, accommodation facilities, tours, free medication, and any other facilities. Such gratification includes any gifts obtained within the country or outside of the country, and includes those that are sent via electronic media or without the help of electronic media. Under Article 13 of the Anti-Corruption Law, a party who gave any gift or promise to a state official, knowing well of their authority or power vested in their position or capacity, is subject to a criminal sanction in the form of imprisonment for a maximum of three years or fine in the maximum amount of IDR 150 billion. In practice, gratification is also considered to be within the scope of prohibited action under Article 13 of the Anti-Corruption Law. There are numerous examples where Article 13 is used by the authorities to penalize gratification actions (giving a sum of money, benefits, etc.) by businesses.

### **Sponsorship**

In general, provision of sponsorship by a pharmaceutical company to a HCP is specifically regulated under Ministry of Health (“**MOH**”) Regulation No. 58 of 2016 on Sponsorship for Healthcare Professionals (“**MOH Regulation 58**”) which took effect as of 29 November 2016.

Based on MOH Regulation 58, sponsorship is defined as follows:

*“Provision of support in any form of assistance and/or activities in order to increase knowledge that is undertaken, organized, sponsored by pharmaceutical companies/industries, medical device companies/industries, medical laboratory device companies/industries or other companies/industries, and that is transparent and accountable (Read: No conflict of interest).”*

Despite the above, MOH Regulation 58 limits the form of the sponsorship that can be provided to HCPs.

According to Article 4 of MOH Regulation 58, any sponsorship provided to a HCP must meet the following principles:

- (a) it does not influence the independence of the HCP in providing health services
- (b) it is not in the form of cash or cash equivalent
- (c) it is not provided directly to individuals
- (d) it is in accordance with the area of expertise
- (e) it is provided publicly
- (f) it is administered in an accountable and transparent manner

Notwithstanding points (b) and (c) above, sponsorship may be provided in the form of cash or cash equivalent as a fee for a speaker and/or a moderator. Under MOH Regulation 58, “cash” includes check, giro, or biljet.

While payment in cash is still possible, it must be structured as a fee paid to the relevant HCPs for their contribution (i.e., there must be a form of reciprocity or *quid pro quo* between the two). Therefore, grants or charitable donations cannot be given as sponsorship to HCPs, as grants or donations are given for free.

Article 8 of MOH Regulation 58 also provides that HCPs can only receive sponsorship under three capacities:

- (a) HCP as the participant
- (b) HCP as the lecturer/source provider
- (c) HCP as the moderator

The following are the forms of sponsorship that can be given to a HCP in case the HCP is attending as a participant:

- (a) cost of registration
- (b) travel ticket
- (c) accommodation

The following are the forms of sponsorship that can be given to a HCP in case the HCP is attending as a speaker:

- (a) cost of registration
- (b) travel ticket
- (c) accommodation
- (d) speaker honorarium

The following are the forms of sponsorship that can be given to a HCP in case the HCP is attending as a moderator:

- (a) cost of registration
- (b) travel ticket
- (c) accommodation
- (d) moderator honorarium

In conclusion, sponsorship can only be given to a HCP if it is in the form of expense coverage or compensation for the HCP participating or attending a knowledge event (e.g., symposium, seminar, etc.).

## 2. Is there “transparency legislation” relating to payments by pharmaceutical companies to HCPs?

Yes, there is and it is also regulated under MOH Regulation 58 and its implementing regulation.

MOH and the Indonesian Corruption Eradication Commission (*Komisi Pemberantasan Korupsi* or “**KPK**”) are the government authorities who monitor and supervise the implementation of MOH Regulation 58 requirements. MOH Regulation 58 is one of the implementing regulations of Law No. 31 of 1999 on Eradication of Crimes of Corruption as amended by the Anti-Corruption Law. Both of them are required to fulfil the Reporting Obligation due to the need for transparency of gratuities or sponsorship granting.

Both giver and receiver of the sponsorship are required to report the sponsorship to KPK after any sponsorship is received (“**Reporting Obligation**”).

In light to the above, MOH regulates the procedure for Reporting Obligation through Circular Letter No. HK.02.01/MENKES/66/2017 on the Mechanism on Reporting Sponsorship In Accordance With MOH Regulation 58 (“**MOH Circular Letter**”). The MOH Circular Letter provides the following information on how the Reporting Obligation should be done:

- (a) The receiver and the giver of the sponsorship must report to KPK via email, copying in the MOH.
- (b) The receiver of the sponsorship must report to the KPK no later than 30 working days after the sponsorship is received, using the following formats:
  - (i) Institutions not as the organizer, and institutions as the organizer, of the sponsorship must use the format in Attachment I of the MOH Circular Letter in carrying out the Reporting Obligation.
  - (ii) Individual practice HCPs must use the format in Attachment II of the MOH Circular Letter in carrying out the Reporting Obligation.

- (iii) The giver of the sponsorship (i.e., the sponsors) must use the format in Attachment III of the MOH Circular Letter in carrying out the Reporting Obligation.
- (c) In case the HCP receives the sponsorship through an institution, the Reporting Obligation must be done by the institution (not as the organizer of the sponsorship).
- (d) The provider of the sponsorship must carry out the Reporting Obligation to the KPK by filing a report in the form of recapitulation of the sponsorship that the sponsor has provided within a month. The report must be submitted no later than the tenth day of the following month (using the format in Attachment III of the MOH Circular Letter). For instance, if the sponsor wanted to report all of the sponsorship that the sponsor has provided in the month of April, the sponsor must submit the report at the latest on 10 May.
- (e) The report, either from the giver or receiver of the Sponsorship, must be submitted to KPK using the email address: [sponsorship@kpk.go.id](mailto:sponsorship@kpk.go.id), copying in the MOH using the email address: [sponsorship@kemkes.go.id](mailto:sponsorship@kemkes.go.id).
- (f) The report must be submitted in two forms: (i) excel (softcopy) and (ii) pdf format. The pdf format is made by the following steps:
  - (i) produce the sponsorship reporting table and fill out all of the required information in the table (in softcopy form or in a simple word document)
  - (ii) print out the reporting document on plain paper
  - (iii) arrange for the Board of Directors (“**BOD**”) of the company that provides the sponsorship to sign the printed reporting document

***Notes:*** In practice, the BOD may be represented by the president director, one of the directors, or several directors together. This all depends on how it is being governed under the Articles of Association of the company.

- (iv) produce the signed reporting document in pdf format (i.e., scanned copy)
- (v) send the pdf copy of the signed reporting document to the designated email address

The Sponsorship report must be submitted within 14 working days of the issuance date of the MOH Circular Letter or 2 March 2017.

### 3. Can a pharmaceutical company offer giveaways or other gimmicks to a HCP? Is there a specific threshold regulated by law?

Not clearly regulated.

Generally, pharmaceutical companies cannot offer giveaways or other gimmicks to a HCP. Any deliverables must be structured as sponsorship in the form allowed under MOH Regulation 58. The form of sponsorship itself is limited under MOH Regulation 58, to, among others, coverage of the HCP's 'cost of accommodation' to attend a sponsorship event.

There is no exact rule on how the cost of accommodation should be structured. The regulations are also vague on whether non-material offerings would also have risks when provided to HCPs.

Arguably, pharmaceutical companies could offer giveaways or gimmicks as long as they are structured as part of the accommodation expense in a sponsorship event and disclosed in the mandatory Report Obligation submission to the authorities. Otherwise, pharmaceutical companies should avoid directly giving any giveaways or gimmicks to HCPs.

**4. Can a pharmaceutical company sign a service contract (such as for speaking at and chairing meetings, translating medical documents, writing medical articles and/or giving medical training) with a HCP?**

Please see No. 1 above, the answer is no. Signing a service contract would be considered as entering into a cooperation under BPOM Decision 05. The above comments on gifts are also applicable to the fees payable to the HCP.

In the case of a civil servant, the contract will be unlawful if given as quid pro quo for violating the HCPs' duty as civil servants. If the HCP is a civil servant, approval from their superior is probably required.

**5. Are HCPs required by law to obtain a written pre-approval from their employer to be able to attend an event organized by a pharmaceutical company?**

Yes, and the event will be considered as a sponsorship given by the pharmaceutical company.

Article 7 of MOH Regulation 58 requires a HCP to obtain the assignment or pre-approval from their superior prior to their attendance of an event that is organized by a pharmaceutical company. In line with this, the assignment or pre-approval must be in accordance with their area of expertise. Note that the purpose of the event must be to increase the knowledge of the HCP in order for it to be considered a sponsorship.





## Japan

Hideo Norikoshi, Kengo Nishigaki and Rie Kuwabara

### 1. Can a pharmaceutical company provide gifts to a HCP?

Yes, but pharmaceutical companies are required to properly observe the relevant rules.

In Japan, self-regulation plays an important role in governing the provision of gifts to a HCP.

The Fair Competition Code of the Ethical Drug Manufacturing Industry (“**FCC**”) in Japan prohibits unfair solicitation of customers to ensure voluntary and rational selection of products by general consumers and to promote fair and orderly competition among business operators. To this end, it restricts the offering of gifts and monetary benefits in the form of a premium as a means to induce unfair transactions. Various factors must be taken into account when a pharmaceutical company offers a gift to a HCP. For example, whether the gift may affect the proper use of drugs, whether it may be perceived by society as interfering with the neutrality of prescriptions and whether it may ruin the socially respected role of drugs, which are life-related products.

On the other hand, the Japan Pharmaceutical Manufacturers Association’s (“**JPMA**”) Code of Practice (“**CoP**”), a voluntary industry code, prohibits the provision of almost all gifts and/or cash etc., to a HCP regardless of whether they are inexpensive or not. Generally, the giving of such gifts is strongly discouraged.

## 2. Is there “transparency legislation” relating to payments by pharmaceutical companies to HCPs?

The Clinical Research Act came into force on 1 April 2018. Pharmaceutical companies are now required to publish information on the provision of research grants and other payments made in connection with specified clinical researches in the preceding fiscal year, which starts on or after 1 October 2018, within one year from the end of each fiscal year.

There are also industry self-regulated standards. The JPMA has published transparency guidelines and requests its member companies to observe the appropriate standards set out therein. This transparency guideline has been an industry practice standard in Japan. Compliance with the transparency guidelines is on a voluntary basis. In practice, most pharmaceutical companies who join JPMA follow the transparency guidelines and disclose necessary information on their website.

## 3. Can a pharmaceutical company offer giveaways or other gimmicks to a HCP? Is there a specific threshold regulated by law?

Giveaways or other gimmicks in Japan are considered as gifts for the purposes of the FCC and CoP. Within the rules set out in Section 1 above, a pharmaceutical company may be allowed to provide the following, but only at very infrequent intervals:

Promotional aids of a minimal value (i.e., approximately JPY 3,000) and quantity may be provided or offered to a HCP if relevant to the practice of the HCP.

An amendment to the CoP came into force on 1 January 2019, prohibiting the provision of almost all giveaways or gimmicks (i.e., postcards, mouth pads and calendars) to a HCP. Under this CoP, a

pharmaceutical company may be allowed to offer pens and notebooks for the purpose of taking notes at a company-sponsored seminar. However, most pharmaceutical companies are no longer offering giveaways or other gimmicks.

**4. Can a pharmaceutical company sign a service contract (such as for speaking and chairing at meetings, translating medical documents, writing medical articles and/or giving medical training) with a HCP?**

A pharmaceutical company may enter into a contract with a HCP, as long as the nature of the service to be provided by the HCP is reasonable and socially acceptable, and the amount of consideration for the service is reasonable and properly reflects the fair market value of the service rendered.

Under the Rules of Ethics for Government Officials, or other similar rules which apply to HCPs who work in the public sector, HCPs must obtain pre-approval from their ethics officer or other supervisor.

**5. Are HCPs required by law to obtain written pre-approval from their employers to be able to attend an event organized by a pharmaceutical company?**

When HCPs in the public sector receive any remuneration by attending an event, pre-approval will be required. In this case, HCPs in the public sector will be obliged to submit all documents that the employer requests for the approval process.

There are no established rules in this regard to govern HCPs working in a private setting.

Last Edited: September 2019

# Malaysia



## Malaysia

Kherk Ying Chew and Adeline Lew

### 1. Can a pharmaceutical company provide gifts to a HCP?

#### Malaysian Anti-Corruption Commission Act 2009 (“MACC”)

Malaysia law does not specifically govern interactions with HCPs, but, in certain circumstances, the MACC may apply. Under the MACC, it is an offense for any person to corruptly give, promise or offer to any person any gratification as an inducement to or as a reward for, or otherwise on account of any person or officer of a public body, doing or forbearing to do anything related to any matter or transaction actual or proposed or likely to take place.

The MACC has been drafted broadly; hence, providing material gifts to HCPs may constitute an inducement or a reward. In addition, section 21 of the MACC prohibits bribery of officers of public bodies. The term “public body” includes, without limitation, government, local and statutory authorities; government departments, services or undertakings; trade unions; youth societies; sports bodies; co-operative societies, and companies or a subsidiary over or in which any of the same has a controlling power of interest. HCPs who work in the public sector are deemed to be officers of public bodies and, as such, providing gifts to such HCPs may contravene section 21.

It is also worth noting that a new corporate liability under section 17A of the MACC has recently been introduced. This new section imposes criminal liability on commercial organizations (which includes Malaysia companies and foreign companies conducting business in Malaysia) if an associated person corruptly gives any gratification with intent to obtain or retain business, or an advantage in the conduct of business, for the commercial organization. In this regard, an “associated person” includes directors and employees, and may extend to third-party

service providers. However, it is a defense if the organization demonstrates that it has adequate procedures in place designed to prevent associated persons from undertaking corrupt practices. This section has not come into force, although it is anticipated to be effective from June 2020.

The Code of Pharmaceutical Marketing Practices for Prescription (Ethical) Products issued by the Pharmaceutical Association of Malaysia (“PHAMA Code”)

The pharmaceutical industry in Malaysia self-regulates its promotional activities. The PHAMA Code generally provides that inappropriate financial or benefit-in-kind should not be offered to HCPs to influence HCPs’ prescribing practices. Particularly, the PHAMA Code prohibits the following items:

- Cash, cash equivalents or personal services, as well as gifts for HCPs’ personal benefit (section 7.6.1)
- Promotional aids in relation to the promotion of prescription-only medicine (section 7.6.2)
- Gifts of cultural courtesy (section 7.6.4)

With regards to promotional aids, kindly note that section 7.6.2 of the PHAMA Code states that:

- Pens and notepads without the name of any medicine, campaign names, tag lines and logos of therapeutic area may be provided in a company-organized event or third-party event for the purpose of taking notes during the meeting. Pens and notepads may bear the name of the company providing them, must be no more than MYR 15 per item, and are distributed only as necessary.
- A thumb drive is allowed only where it is necessary to provide information to the HCP, and its storage size must correspond to the size of the information provided.

With regards to medical educational materials, section 7.6.3 states that:

- Information or educational items provided for HCPs are permitted provided that:
  - The value must not exceed MYR 1,500 per year per institution or HCPs.
  - The items are primarily for educational purposes and do not have independent value.
  - While company branding is permitted, the items must not bear any product branding, product campaign names, tag lines and logos of therapeutic areas.
- Information or educational items provided for educating patients about diseases and treatments are permitted provided that:
  - The items are primarily for educational purposes and do not have independent value.
  - The items may include the company name but must not be product-branded, unless the product's name is essential for correct use of the item by the patient.
- Items of medical utility to enhance the provision of medical services and patient care are permitted provided that:
  - The items are of modest value, do not exceed MYR 500 per item per HCP, do not offset routine business practices and are beneficial to enhancing the provision of medical services and patient care. Examples of routine business expenses include items such as stethoscopes, surgical gloves, blood pressure monitors and needles.
  - The items are offered on an occasional basis only.



- The items bear only the company's branding and not the product branding, product campaign names, tag lines and logos of therapeutic areas.

Compliance with the PHAMA Code is on a self-regulatory basis, and while breaches of it will attract a fine of up to MYR 50,000 for a one-off breach or MYR 100,000 for a repeated breach, there is no corresponding mechanism to enforce the fine. Further, transgressions of the Code may also result in adverse publicity.

Code of Conduct for Pharmacists and Bodies Corporate issued by the Pharmacy Board Malaysia (“PBM Code”)

For completeness, also to be considered is the PBM Code which regulates conduct from the perspective of pharmacists. Section 1.1.2(h) states that pharmacists are not to accept inducement from suppliers that could reasonably be perceived as affecting pharmacists' independent professional judgment. In addition, section 1.8.1 requires pharmacists to avoid situations whereby they, by accepting any financial or material inducement, would compromise their professional judgment on the choice of drug for their patient or client.

Kindly note that a new Code of Ethics 2018 will replace the PBM Code with effect on 1 January 2020. Under the new code, pharmacists shall be ethical, honest and trustworthy, and shall not have a conflict of interest, which affects their judgment or decision-making at work, their job duties or their loyalty to their employer, in particular:

- The pharmacist shall not accept gifts, rewards or hospitality that may affect, or be seen to affect, his/her professional judgment.
- The pharmacist shall not accept financial or material inducement which compromises his/her professional judgment on the choice of drug for his/her patient or client.

Code of Professional Conduct adopted by the Malaysian Medical Council (“**Professional Conduct Code**”)

Additionally, under the Professional Conduct Code, Part II, Clause 1.6.2, practitioners should not accept from a pharmaceutical firm monetary gifts or loans or expensive items of equipment for his/her personal use. Clause 1.6.1 also requires practitioners to exercise independent professional judgment when choosing the appropriate drug or appliance that best serves the medical interests of the patient. The Professional Conduct Code should be read in conjunction with the Guidelines on Relationships between Doctors & The Pharmaceutical Industry 2006 (“**2006 Guidelines**”), which provides that:

- Benefits or subsidies received from pharmaceutical companies must leave the doctor’s independence of judgment unimpaired.
- Any arrangements between the doctor and a pharmaceutical company should be open and transparent.
- Non-service-oriented items should, in general, not be accepted by doctors.
- All hospitality for educational and scientific meetings must be simple and modest and interactions with doctors should successfully withstand public and professional scrutiny.

## 2. Is there “transparency legislation” relating to payments by pharmaceutical companies to HCPs?

There is no specific “transparency of payment to healthcare professionals” legislation of general application in Malaysia.

However, the 2006 Guidelines stress the need for openness and transparency in dealings between HCPs and pharmaceutical companies and, in many cases, require disclosure of financial or other

arrangements to institutions, ethics committees, patients, potential research subjects and others. Such disclosures do not in themselves imply the existence of conflicts of interest, but merely allow public scrutiny of possible dualities of interest to ensure that such conflicts do not develop and do not cloud primary clinical objectives. That said, please note that such obligation to disclose falls upon the HCP.

Doctors in the public healthcare system are, by reason of their being civil servants, governed by the Public Officers (Conduct and Discipline) Regulations 1993 (“1993 Regulations”). Under the 1993 Regulations (4), doctors are not permitted to conduct themselves in a way that would cause reasonable suspicion that they have used their public position for their personal advantage. Over and above the codes and Regulations, there is the Malaysian Anti-Corruption Commission Act 2009, which applies to corrupt activities generally.

### 3. Can a pharmaceutical company offer giveaways or other gimmicks to a HCP? Is there a specific threshold regulated by law?

Please refer to the above information on gifts. Although giveaways or gimmicks are not specifically referred to, general principles similar to the above would apply.

### 4. Can a pharmaceutical company sign a service contract (such as for speaking and chairing at meetings, translating medical documents, writing medical articles and/or giving medical training) with a HCP?

Yes, the law and regulations in Malaysia do not restrict this arrangement. Malaysian law does not require a HCP to get pre-approval from his/her employer to sign such contracts with a pharmaceutical company.

The PHAMA Code allows pharmaceutical companies to engage HCPs as consultants and advisers for services, such as speaking at and/or chairing meetings and events, involvement in training services and participation at advisory board meetings where such participation involves remuneration, provided that such arrangements are genuine and fulfills the following criteria to the extent relevant to the particular arrangement:

- A written agreement must be agreed prior to the commencement of the services, which specifies the nature of the services to be provided and the basis for payment of those services.
- A legitimate need for the services must be clearly identified and documented in advance.
- The criteria for selecting consultants must be directly related to the identified need and the consultants must have the expertise necessary to provide the service.
- The number of consultants retained must not be greater than the number reasonably necessary to achieve the identified need.
- The hiring of the consultant to provide the relevant service must not be an inducement to prescribe, recommend, purchase, supply, and/or administer any medicine.
- The fair market value of the services provided is MYR 1,500/engagement/day with up to maximum MYR 3,000/multiple engagement/day.
- If it concerns local speakers at international events held locally or outside Malaysia, members are advised to refer to their own company's internal code. The same proposal on a signed contract remains.

- If it concerns international speakers, then members are advised to check with the speaker's home country code and apply accordingly. The same proposal on a signed contract remains.
5. Are HCPs required by law to obtain written pre-approval from their employers to be able to attend an event organized by a pharmaceutical company?

No, Malaysian law and regulations do not restrict this arrangement.

# Myanmar



## Myanmar

Andre Gan and Chadd Concepcion

### 1. Can a pharmaceutical company provide gifts to an HCP?

Gift giving is allowable in general, but gifts have to comply with existing guidelines.

The Myanmar Medical Council is the governing body for the medical profession and it issues rules and regulations for the profession. One such issuance is the Medical Ethics for Medical Profession (**Medical Ethics Guidelines**) which provides that a medical practitioner should not ask for or accept any material gifts or loans from companies that sell or market drugs or appliances, except those of insignificant value. We note however that the Medical Ethics Guidelines do not provide any more detail on what constitutes “insignificant value”, but as we will discuss below further guidelines from the Myanmar government may provide more information on this matter.

The Myanmar Anti-Corruption Law was amended in 2018, and the key change relevant to this discussion is the definition of what would constitute an act of “corruption”. Briefly, in our plain interpretation of the law, the new definition of corruption can now be interpreted to include transactions between private persons in the context of making bribes or otherwise consequently abusing position or authority. Additionally, it provides that the Anti-corruption Commission -- the chief regulatory body of the Anti-Corruption Law -- can order private organizations to establish and follow a code of conduct to prevent corruption. We understand these provisions to mean that Myanmar’s Anti-Corruption Laws and regulations are meant to be observed by both the public and private sector.

That said, a general “guidance” instrument issued from the President’s Office in April 2016 (**Gift Guidelines**) provides that small gifts given in

the course of business dealings may not constitute corruption. These include gifts with a value not exceeding MMK 25,000 (with a yearly maximum threshold of MMK 100,000), or not exceeding MMK 100,000 in religious occasions such as during Thadinkyut or Christmas.

This considered, gift giving in general should be exercised with proper caution and always only after having exercised due diligence for compliance.

## 2. Is there a “transparency legislation” relating to payments by pharmaceutical companies to HCPs?

There is no specific law or regulation covering payments by pharmaceutical companies to HCPs. However, in the absence of specific legislation, we refer to the Gift Guidelines which may apply to payments made to HCPs, particularly where the HCP is in the public sector.

According to the Gift Guidelines, public officials are expressly prohibited from accepting gifts that are given due to their position. Specifically, they may not accept gifts from a company or individual seeing to carry on business with the organization they supervise.

As mentioned briefly above, the Gift Guidelines provide more information on what constitutes allowable gifts. Gifts costing not more than MMK 25,000 are permitted, though a public official may not accept more than a total value of MMK100,000 per year from any one company or individual. Another exception allows for gifts given on special traditional holidays, such as Thadinkyut or Christmas, though they may not be over a value of MMK100,000. Gifts given by family members or friends and not related to the person’s public office are also allowed.



### 3. Can a pharmaceutical company offer giveaways or other gimmicks to an HCP? Is there a specific threshold regulated by law?

Again, there is no specific law or regulation which covers this.

As stated above, the Medical Ethics Guidelines provide that medical practitioners 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. By analogy, we understand this same guideline on “gifts” to apply to any promotional activity, including giveaways and other gimmicks.

Further, pharmaceutical companies dealing with public service employees or organizations should take care to conduct promotional activities within the thresholds as provided in the Gift Guidelines.

### 4. Can a pharmaceutical company sign a service contract (such as for speaking and chairing at meetings, translating medical documents, writing medical articles and/or giving medical training) with an HCP?

From our review of relevant laws and regulations, we found no restriction for pharmaceutical companies to engage in services to be provided to an HCP.

That said, the Medical Ethics Guideline mentions that medical professionals may accept personal travel grants and hospitality from pharmaceutical companies for conferences or educational meetings as long as the main purpose of the event is educational.

Further, if the HCP is in public services or a public service employee, seeking prior approval from the Myanmar Medical Council is recommended to ensure compliance with ethics guidelines.

5. Are HCPs required by law to obtain a written pre-approval from their employer to be able to attend an event organized by a pharmaceutical company?

We did not find any law or regulation which imposes such a requirement.

It is possible that the employment contract or internal policies of the HCP may impose such a requirement, and if so, such restriction would be limited to the covered employer and employee. In a similar manner, if the HCP is in the public service, the HCP may adopt internal rules and regulations which may apply to its staff. In this case, it is recommended to request approval from the HCP or the Myanmar Medical Council to ensure compliance with internal rules and regulations, and to avoid any conflicts of interest.



## Philippines

Christina Macasaet-Acaban, Michael Macapagal and Lara Camille Lee

### 1. Can a pharmaceutical company provide gifts to a HCP?

Yes, but with exceptions.

Philippine regulations prohibit giving healthcare professionals (HCPs) items that do not have any direct patient benefit, or are not related to the HCP's work.

However, it is permissible to provide HCPs with (i) promotional aids of modest value, which are relevant to the HCP's practice or to patients' education; and (ii) modest items of medical utility, such as textbooks, subscriptions to medical journals or anatomical models that benefit patients or serve a genuine educational function for the HCP.

Furthermore, HCPs in the public sector are subject to the Philippine Anti-Bribery and Anti-Corruption Law, which prohibits the giving of gifts to public officials. By way of exception, unsolicited gifts of nominal value, which are not given by reason of the HCP's office/function may be allowed.

#### **HCPs in the private sector**

The Philippine Department of Health (DOH) issued Administrative Order No. 2015-0053, entitled "Implementing Guidelines on the Promotion and Marketing of Prescription Pharmaceutical Products and Medical Devices" ("**Guidelines**") to implement the "Mexico City Principles for Voluntary Codes of Business Ethics in the Biopharmaceutical Sector" and the "Kuala Lumpur Principles: Medical Device Sector Codes of Ethics" which are voluntary codes of ethics for the medical device and biopharmaceutical sectors, respectively. The Guidelines apply to all individuals and entities ("**Covered Entities**")

that disseminate or publish information on, advertise, promote, engage in sponsorship activities relating to, or otherwise market, prescription pharmaceutical products and medical devices (“**PPMDs**”).

In addition to the Guidelines, interactions between Covered Entities and HCPs and healthcare organizations may be covered by industry association codes of ethics with respect to association members.

The Guidelines provide mandatory standards for interactions, particularly in respect of the promotion and marketing of PPMDs.

The FDA may recommend filing the appropriate charges with the concerned government agency or appropriate court for violations of the Guidelines. Furthermore, a violation of the Guidelines may be a ground for filing appropriate administrative charges and/or imposition of administrative sanctions such as, but not limited to, imposition of fines, suspension, cancellation or revocation of any license, permit or registration issued by the FDA.

Aside from the Guidelines, the Code of Ethics of the Philippine Medical Association (“**PMA Code**”) allows a physician to accept only gifts of reasonable value that primarily entail benefit to patient care or are related to physicians’ work from a health product company. Violation of the PMA Code may lead to administrative sanctions against the HCP.

PPMD companies that are members of the Pharmaceutical and Healthcare Association of the Philippines (PHAP), a non-stock, non-profit organization with members consisting of companies engaged in research and development, manufacturing, retail and distribution of pharmaceutical products and medical devices, are also bound by the PHAP Code of Pharmaceutical Marketing Practices (“**PHAP Code**”). The latest version of the PHAP Code became effective on February 2019. The PHAP Code provides, among other things, that no financial benefit or benefit in kind (including grants, scholarships, subsidies, support, consulting contracts or educational or practice-related items)

may be provided or offered to a HCP in exchange for prescribing, recommending, purchasing, supplying or administering products, or for a commitment to continue to do so. Nothing may be offered or provided in a manner or on conditions that would inappropriately influence a HCP's prescribing practices. Gifts of any kind for the personal benefit of the HCP are not allowed regardless of value, kind or occasion (i.e., birthday, Christmas, anniversary or other occasions). Sanctions for violations of the PHAP Code may take the form of one or more of the following: (i) The requirement that the subject company take immediate action to discontinue or modify any practice that is determined to constitute a breach of the PHAP Code; (ii) the issuance of a compliance statement signed or authorized by the general manager, which includes the date on which the material in violation of the PHAP Code was finally used or appeared and/or the last date on which the activity in breach of the PHAP Code took place; (iii) the imposition of a fine on the subject company ranging from PHP 200,000 for the first offense to PHP 750,000 per offense for successive offenses of the same nature or within the same section of the PHAP Code within a 12-month period.

### **HCPs in the public sector**

The Guidelines apply to HCPs in the public sector. In addition, the Philippine Anti-Bribery and Anti-Corruption Law prohibits the giving of gifts, broadly defined as anything of value, to public officials. Certain laws allow, by way of exception, unsolicited gifts of nominal value, which are not given due to the HCP's office/function. Additionally, under Republic Act No. 11032 (or the Ease of Doing Business Act of 2018), HCPs in the public sector are prohibited from becoming a "fixer" or colluding with one. A fixer is defined as any individual, whether or not officially involved in the operation of a government office or agency, who has access to people working in the office or agency, and whether or not in collusion with them, facilitates speedy completion of transactions for pecuniary gain or any other advantage or consideration.

## 2. Is there “transparency legislation” relating to payments by pharmaceutical companies to HCPs?

There is no specific “transparency of payment to healthcare professionals” legislation in the Philippines.

However, some requirements under the Guidelines may amount to a form of disclosure. For instance, if a covered entity sponsors HCPs for professional development events, the covered entity must submit details on travel and sponsorship to the FDA. If the sponsored HCP is a government employee, the HCP must file a post-travel report with his/her agency.

HCPs in the public sector may be subject to disclosure requirements imposed by his/her particular agency’s regulations or as a result of practice in that agency. DOH officials/employees, for instance, must record benefits valued over approximately USD 215 in the Registry Book of Gifts when “[received] in the workplace.” This regulation will likely be revised to take into account the prohibition against giving gifts to HCPs.

## 3. Can a pharmaceutical company offer giveaways or other gimmicks to a HCP? Is there a specific threshold regulated by law?

Giveaways may be considered as “gifts.” See discussion in (1) above.

In addition, under the PHAP Code, a covered entity may offer items of medical utility if such items are of modest value, do not offset routine business practices and are beneficial to enhancing the provision of medical services and patient care. Items such as stethoscopes, surgical gloves, blood pressure instruments and needles are examples of routine business expenses and they are expected to be supplied by the HCP themselves or their employers. The maximum value for items of medical utility should not exceed PHP 8,000.

Under the PHAP Code, providing promotional aids, which are non-monetary items given for a promotional purpose, in relation to the promotion of prescription-only medicines and medical devices is prohibited. Printed promotional materials are not considered promotional aids.

Promotional aids of minimum value and quantity may be provided or offered to HCPs solely for the promotion of over-the-counter medicines, only if relevant to the practice of the HCP and the maximum value should not exceed PHP 1,000.

#### 4. Can a pharmaceutical company sign a service contract (such as for speaking and chairing at meetings, translating medical documents, writing medical articles and/or giving medical training) with a HCP?

The Guidelines allow a PPPMD company to engage consultants and speakers, subject to the following requirements:

- The engagement is covered by a written contract that specifies the nature of the services rendered by the HCP and consideration for such services.
- The criteria for consultant selection is based on identified needs and expertise.
- The contracting covered entity keeps a record of all such transactions.
- Compensation for the service is reasonable and reflects fair market value for the services.
- The consultant or speaker executes and submits to the DOH a “disclosure of any potential or actual conflict of interest” in the form annexed to the Guidelines.



- Information on the arrangement will be made public if and when requested by the DOH for legitimate purposes.

Whether or not pre-approval is required would depend, (i) for HCPs in the private sector, on the HCP's employer; and (ii) for HCPs in the public sector, on various factors (e.g., nature of the contract and the rules and regulations of the particular agency involved.)

## 5. Are HCPs required by law to obtain written pre-approval from their employers to be able to attend an event organized by a pharmaceutical company?

There is no legal or regulatory requirement for HCPs in the private sector to obtain written pre-approval from their employer to attend events organized by pharmaceutical companies. However, an employer may impose these requirements within the company.

With respect to HCPs in the public sector, pre-approval is generally required.

# Singapore



## Singapore

Andy Leck and Ren Jun Lim

### 1. Can a pharmaceutical company provide gifts to a HCP?

Under section 5 of the Prevention of Corruption Act (Cap. 241) (the **PCA**), gifts cannot be corruptly received, given or agreed to be received/given for the doing of or for preventing the doing of anything in relation to any actual or proposed transaction.

No gifts shall be offered or given to members of the medical profession for the purposes of sales promotions (Singapore Association of Pharmaceutical Industries Code (the **SAPI Code**)).

Cash payments/cash equivalents (e.g., gift certificates), gifts for the HCP's personal benefit and cultural courtesy gifts (e.g. mooncakes, mandarin oranges, etc.) are not allowed (SAPI Code section 7.5.1). In this regard, any back-door gifts, whether indirectly provided through a third party or in the form of a financial donation and/or gift to medical societies, hospitals or a clinic's social events, are similarly prohibited.

Promotional items relating to prescription-only medicines are not allowed (SAPI Code section 7.5.2(i)).

Promotional aids in the form of pens and notepads may nevertheless be provided, albeit only in the context of company-organised events for the purpose of taking notes. The stationeries must have no product branding, and be of minimal value with only the necessary quantity being distributed (SAPI Code section 7.5.2(ii)).

Food items and drinks that are a part of a discussion may only be distributed to doctors in the course of day-to-day promotional activities and should be limited to no more than SGD20 (USD15) per doctor (SAPI Code section 7.5.2(v)).

Congratulatory or condolence flowers and messages in any form of media directly to or on behalf of a HCP or medical centre are strictly prohibited (SAPI Code section 7.5.2(iv)).

Although the prohibition under Article 7.5.2 of the SAPI Code, like Article 7.5.1, is in relation to prescription-only medicines, the provision/offer of promotional aids for over-the counter and pharmacy medicines if relevant to the practice of the HCP is subject to restrictions. Promotional aids for the promotion of such medicines can only be provided/offered to the HCP if they are of minimal quantity valued at no more than SGD20 (USD15).

A doctor shall not ask for nor accept extravagant gifts, hospitality or other inducements that may affect or be seen to potentially affect his/her judgment in making decisions about patients' treatment. A doctor may nevertheless accept educational materials and items of medical utility of modest value if they improve patient care (Singapore Medical Council's Ethical Code & Ethical Guidelines (the **SMC Ethical Code**) section I(11)(8)).

## 2. Is there “transparency legislation” relating to payments by pharmaceutical companies to HCPs?

There is no specific “transparency of payment to healthcare professionals” legislation in Singapore.

The principal statute that regulates corrupt activities is the Prevention of Corruption Act (Cap. 241). In brief, the giving of (and receipt) of any gratification “corruptly” is prohibited.

Industry guidelines may be helpful in determining whether the gratification is given/received with a corrupt intent and purpose.

Relevant industry guidelines include the Singapore Association of Pharmaceutical Industries Code of Marketing Practices, the Singapore Manufacturing Federation Medical Technology Industry Group's Code

of Ethical Conduct for Interactions with Healthcare Professionals and the Singapore Medical Council's Ethical Code and Ethical Guidelines.

### 3. Can a pharmaceutical company offer giveaways or other gimmicks to a HCP? Is there a specific threshold regulated by law?

Giveaways or gimmicks may count as gifts under Singapore law. Gifts cannot be corruptly received/given, or agreed to be received/given for the doing of or for preventing the doing of anything in relation to any actual or proposed transaction (PCA section 5).

Items of medical utility may be offered or given free of charge if such items are of modest value and are beneficial to enhancing the provision of medical services and for patient care, with the value of such items limited to no more than SGD 200 (USD 150). These items may include the company's name, but must not be product-branded, unless the product's name is essential for the correct use of the item by the patient (SAPI Code section 7.5.3).

A doctor shall not ask for nor accept extravagant gifts, hospitality or other inducements that may affect or be seen to potentially affect his/her judgment in making decisions about patients' treatment. As outlined above, a doctor may nevertheless accept educational materials and items of medical utility of modest value if they improve patient care (SMC Ethical Code section I(11)(8)).

### 4. Can a pharmaceutical company sign a service contract (such as for speaking and chairing at meetings, translating medical documents, writing medical articles and/or giving medical training) with a HCP?

The subject matter of the service contract (e.g., training or conferences) cannot be corruptly received/given, or agreed to be

received/given, for the doing of or for preventing the doing of anything in relation to any actual or proposed transaction (PCA section 5).

The SAPI Code and SMC Ethical Code allow for pharmaceutical companies to enter into such relationships with HCPs, subject to certain limits on sponsorship, hospitality, etc.

## 5. Are HCPs required by law to obtain written pre-approval from their employers to be able to attend an event organized by a pharmaceutical company?

There are no restrictions under the SAPI Code and the SMC Ethical Code. However, the employers of HCPs may have contractual restrictions on such activities or internal codes of conduct regulating such activities. These activities should be primarily focused on education or research, and not on various other leisure activities such as extravagant meals and entertainment.

A doctor should ensure that his/her participation in sponsored conferences does not occur in such a way as to appear to endorse such products or to persuade patients or the public to use the products. Apart from identification and establishment of credentials, no details of services provided by the doctor or service details shall appear in any way in relation to such participation.

A doctor who is sponsored by a company to participate in an educational event must declare such sponsorship to the audience. He must also ensure that the support he receives is limited to that necessary to facilitate his attendance, and does not include support for unrelated activities, additional stay, or the costs of any accompanying persons (SMC Ethical Code section I(11)).

# Taiwan



## Taiwan

Belle Chiou

### 1. Can a pharmaceutical company provide gifts to a HCP?

Pharmaceutical companies are not expressly prohibited from providing gifts to HCPs under Taiwan laws and regulations. Nevertheless, the provision of gifts to HCPs by pharmaceutical companies are generally not allowed under the industry code.

The IRPMA Code of Practice (“**IRPMA Code**”) promulgated by the International Research-Based Pharmaceutical Manufacturers Association prescribes the following:

- Payments in cash, cash equivalents (such as gift certificates), personal service (any service unrelated to the HCP’s profession and that confers a personal benefit to the HCP) or gifts for the personal benefit of HCPs (such as sporting or entertainment tickets, electronic items, etc.) must not be provided or offered to HCPs.
- Since 16 May 2018, promotional aids should not be provided to HCPs either. A promotional aid is a non-monetary item, printed with the names of companies and/or products, given to HCPs for a promotional purpose.
- Items of medical utility may be offered or provided if such items are of modest value, do not offset routine business practices and are beneficial to enhancing the provision of medical services and for patient care. A medical utility must not bear the name of a product (both branded or of a generic name) but may bear the company logo.

The IRPMA Code has been published in Taiwan for more than 12 years. In addition to member companies, many pharmaceutical



companies and medical device companies that are not members of the IRPMA also established their own compliance policies by referring to this code. Therefore, although the IRPMA Code does not have the force of law, the principles and restrictions set forth thereunder to some extent have become parts of the prevailing practice in Taiwan, and compliance with this code will help show that the promotional/marketing activity in question was not conducted “corruptly” under the anti-bribery legislation of Taiwan.

## 2. Is there “transparency legislation” relating to payments by pharmaceutical companies to HCPs?

There is neither transparency legislation, like the US Sunshine Act, nor industry self-regulated standards in this regard in Taiwan.

## 3. Can a pharmaceutical company offer giveaways or other gimmicks to a HCP? Is there a specific threshold regulated by law?

Effective from 16 May 2018, provision of promotional aids (such as gimmicks) to HCPs by a pharmaceutical company is not allowed under the IRPMA Code.

## 4. Can a pharmaceutical company sign a service contract (such as for speaking and chairing at meetings, translating medical documents, writing medical articles and/or giving medical training) with a HCP?

Yes, one or more HCPs may be engaged by a pharmaceutical company as consultants and advisors for services such as speaking at and/or chairing meetings and events, involvement in medical/scientific studies, clinical trials or training services, participation in advisory board meetings, and participation in market

research where such participation involves remuneration. The arrangements covering these genuine consultancies or other services must, to the extent relevant to the particular arrangement, fulfill all the following criteria set forth in the IRPMA Code:

- A written contract or agreement must be agreed in advance of the commencement of the services, which specifies the nature of the services to be provided and the basis for payment of those services.
- A legitimate need for the services must be clearly identified and documented in advance.
- The criteria for selecting consultants must be directly related to the identified need and the consultants must have the expertise necessary to provide the service.
- The number of consultants retained must not be greater than the number reasonably necessary to achieve the identified need.
- The hiring of the consultant to provide the relevant service must not be an inducement to prescribe, recommend, purchase, supply, and/or administer any medicine.
- Compensation for the services must be reasonable and reflect the fair market value of the services provided.

Consent from the HCP's employer is likely required for the HCP to enter into such a service contract, depending on the employment contract between the HCP and his/her employer or upon the employer's internal rules, regardless of whether the HCP is a public- or private-sector employee.

## 5. Are HCPs required by law to obtain written pre-approval from their employers to be able

## to attend an event organized by a pharmaceutical company?

Whether or not prior approval from the HCP's employer is required for the HCP to attend an event organized by a pharmaceutical company will depend on the employment contract between the HCP and his/her employer or upon the employer's internal rules, regardless of whether the HCP is a public- or private-sector employee.

# Thailand



## Thailand

Peerapan Tungsuwan, Yuthana Sivaraks and Praween Chantanakomes

### 1. Can a pharmaceutical company provide gifts to a HCP?

#### **Thai law**

In the case of HCPs deemed to be government officials, they may be provided gifts on a traditional, customary or cultural occasion, or on an occasion in which the manners practiced in society require the giving of such gifts.

Regardless, no government official may receive any gifts with a value in excess of THB 3,000 (approximately USD 97) on a single occasion from a person not related to the government official.

For HCPs deemed to be government officials, it is required that there be no corrupt intent behind the provision of gifts.

The above requirement does not apply to HCPs not deemed to be government officials.

However, under the current Medical Council Regulations on the Preservation of Medical Ethics, all HCPs (whether deemed government officials or not) shall not accept any gifts worth more than THB 3,000 from business operators who operate businesses related to healthcare products.

Therefore, any gifts provided to HCPs not deemed to be government officials should still be of a nominal value and should not be given in return for the pharmaceutical company retaining or obtaining business, or to gain an improper or unfair advantage.

## **PReMA Code**

Pharmaceutical companies in Thailand may be members of the Pharmaceutical Research & Manufacturers Association (PReMA).

PReMA has issued a Code of Practice, 12th edition, 2019 (“**PReMA Code**”). Members of PReMA are required to adopt the requirements of, and comply with, the PReMA Code.

The PReMA Code stipulates that any gifts which are provided to HCPs must never constitute an inducement to prescribe, recommend, supply, sell or administer a pharmaceutical product.

Furthermore, gifts for the personal benefit of HCPs (e.g., sporting/entertainment tickets, electronic items, social courtesy gifts, funeral wreaths, calendars, etc.) are prohibited. However, corporate image items for the public (with no promotional intent and with no linkage to the symbol of the pharmaceutical products) are not prohibited.

The PReMA Code also prohibits the provision or offering of cash (or cash equivalents) and personal services (i.e., any type of service which is unrelated to the HCP’s profession and that confers a personal benefit to the HCP) to HCPs.

### Note:

*The guidelines issued under the PReMA Code further elaborate that members are prohibited from offering monetary donations, sponsoring funeral rites or providing funeral wreaths for the loss of the HCP (or their immediate family members). However, due to cultural and individual beliefs, members may not prohibit their staff from providing wreaths, offering personal monetary donations or sponsoring the funeral rites where it is their personal decision (and where it is undertaken without any hidden purpose).*

## Government-issued ethical guidelines

Recently, the Thai Government has attempted to introduce ethical guidelines in relation to the sales and promotion of drugs and other pharmaceutical products.

The Ministry of Public Health (MOPH) itself has issued a notification providing ethical guidelines for all agencies under its supervision and control ("**MOPH Notification**"). Under the MOPH Notification, HCPs should not receive any gifts except if the value of the gift does not exceed THB 3,000 and the gift is given for a special or customary occasion. Additionally, on 25 March 2015, a Memorandum of Understanding on the Code of Conduct for Sales Promotion in Thailand ("**MOU**") was signed by the relevant stakeholders, including government authorities, professional councils, PReMA and private entities in the pharmaceutical industry. The main purpose of the MOU was to establish standard practices for drug sales promotion across various stakeholders.

As a result of the MOU, the National Drug System Development Committee issued its own ethical guidelines in relation to the sales and promotion of drugs and other pharmaceutical products ("**NDSDC Guidelines**"). The purpose of the NDSDC Guidelines is to create ethical practices for all sectors involved in the drug system, which includes hospitals, pharmacies, business operators, drug sales representatives and academic institutions.

Under the NDSDC Guidelines, HCPs (particularly those who have the authority to order or procure drug products) should not accept any personal benefit from drug sales representatives or pharmaceutical companies. Such personal benefits include gifts. The restrictions also apply to pharmaceutical companies, which should not provide gifts as an inducement for the purchase of drug products.

Notwithstanding the above, it should be noted that the NDSDC Guidelines are intended to create an ethical framework, which may be

taken on by the relevant stakeholders. However, it does not in itself have the force of law.

## 2. Is there “transparency legislation” relating to payments by pharmaceutical companies to HCPs?

### **Thai law**

There is no specific “transparency legislation” relating to payments by pharmaceutical companies to HCPs under Thai law. The main legislation controlling payment to government officials is the Penal Code and the Act Supplementing the Constitution Relating to the Prevention and Suppression of Corruption, B.E. 2561 (A.D. 2018).

### **PReMA Code**

The PReMA Code does contain provisions setting out guidelines for interacting with HCPs, which include matters related to the provision of gifts, sponsorship to attend academic events and the payment of service fees. However, as noted above, the PReMA Code is only adopted by members of PReMA.

### **Government-issued ethical guidelines**

The MOPH Notification also provides a framework for HCPs and institutions to follow in relation to interactions with pharmaceutical companies. However, the MOPH Notification only applies to HCPs and institutions that are under the supervision and control of the MOPH.

The NDSDC Guidelines also provide similar instructions with respect to interactions with HCPs, but again, these are not law that impose specific obligations on the relevant stakeholders.



### 3. Can a pharmaceutical company offer giveaways or other gimmicks to a HCP? Is there a specific threshold regulated by law?

#### **Thai law**

Giveaways or gimmicks for HCPs deemed to be government officials may be subject to the same requirements outlined above on the provision of gifts.

Although giveaways or gimmicks may not be given on a traditional, customary or cultural occasion (e.g., provided at training events held by the pharmaceutical company), the provision of such giveaways or gimmicks may still be acceptable as common industry practice, on the condition that the giveaway or gimmick is not provided with any corrupt intent.

Any giveaways or gimmicks provided to HCPs deemed to be government officials must be of a nominal value and in no event shall their value exceed THB 3,000.

The above requirement does not apply to HCPs not deemed to be government officials.

However, under the current Medical Council Regulations on the Preservation of Medical Ethics, all HCPs (whether deemed government officials or not) shall not accept any giveaways or gimmicks worth more than THB 3,000 from business operators who operate businesses related to healthcare products.

Therefore, any giveaways or gimmicks provided to HCPs not deemed to be government officials should still be of a nominal value and should not be given in return for the pharmaceutical company retaining or obtaining business, or to gain an improper or unfair advantage.

## **PReMA Code**

Under the PReMA Code, giveaways or gimmicks are non-monetary items that are given for promotional purposes.

The PReMA Code stipulates that members must not provide or offer any giveaways or gimmicks to HCPs in relation to the promotion of prescription-only medicines. However, notepads and pens (with the company's logo or name) may be distributed at scientific meetings (but such logo or name shall not be linked with the products' symbols (e.g., the font, artwork or tag line of the products, etc.)).

Giveaways or gimmicks in relation to the promotion of over-the-counter medicines may be provided or offered to HCPs if:

- They are related to the work of the recipient HCP and are of minimal quantity. Giveaways or gimmicks intended for the personal benefit of the HCP (e.g., music CDs, paintings or food baskets, etc.) are not acceptable.
- They serve as brand name reminders (which shall include the brand name of the product, logo or company name). They are not to contain any promotional claims (including promotional tag lines or statements).
- They have a value not exceeding THB 500 and are in line with the FDA's regulations.

## **Government-issued ethical guidelines**

The MOPH Notification and the NDSDC Guidelines do not provide any specific requirements for the provision of giveaways or gimmicks.

However, the same principles that apply to the provision of gifts should also apply to the provision of giveaways or gimmicks.

#### 4. Can a pharmaceutical company sign a service contract (such as for speaking and chairing at meetings, translating medical documents, writing medical articles and/or giving medical training) with a HCP?

##### **Thai law**

There are no laws or regulations that prohibit a pharmaceutical company from entering into a service contract with a HCP, as long as there is a legitimate reason to employ the services of the HCP. There are also no laws or regulations that require HCPs to obtain pre-approval from his/her employer prior to being able to sign a service contract with a pharmaceutical company.

However, for transparency, the pharmaceutical company may inform the HCP's employer of its intent to enter into the service contract with the HCP, specifically in the case of HCPs deemed to be government officials.

It should be further noted that, under the current Medical Council Regulations on the Preservation of Medical Ethics, HCPs cannot accept payment from business operators except for compensation from being a consultant/advisor, speaker fees or research funding.

##### **PReMA Code**

HCPs may be engaged as consultants and advisors for services. The arrangements that cover such services must, to the extent relevant to the particular arrangement, fulfill the following criteria:

- A written contract or agreement must be agreed in advance of the commencement of the services, whereby the contract or agreement shall specify the nature of the services to be provided and the basis for payment of those services.

- A legitimate need for the services must be clearly identified and documented in advance.
- The criteria for selecting the service provider must be directly related to the identified need and the service provider must have the expertise necessary to provide the services.
- The number of service providers retained must not be greater than the number reasonably necessary to achieve the identified need.
- The hiring of the service providers must not be an inducement to prescribe, recommend, purchase, supply and/or administer any medicine.
- Compensation for the services must be reasonable and reflect the fair market value of the services provided.

### **Government-issued ethical guidelines**

Under the MOPH Notification, HCPs under the supervision and control of the MOPH are not permitted to receive money under any circumstances, except as compensation for being a speaker or presenter at an academic event, or if the money is received as research funding. There are, however, no other specific requirements in relation to other forms of service contracts.

The NDSDC Guidelines provide similar restrictions where the HCP should not receive any personal benefit from pharmaceutical companies except in relation to compensation for being a speaker or presenter at an academic event. HCPs can also receive sponsorship for academic research, but this must be provided under the supervision of the medical institution.

## **5. Are HCPs required by law to obtain written pre-approval from their employers to be able**

## to attend an event organized by a pharmaceutical company?

### **Thai law**

There are no laws or regulations that would require a HCP to obtain written approval from the HCP's employer prior to being able to attend an event organized by a pharmaceutical company.

However, in the event that a HCP deemed to be a government official (whether under the supervision of the MOPH or not) will be sponsored by the pharmaceutical company to attend the event, then pre-approval of the HCP's superior must be acquired.

Although the above requirement on sponsorship may not apply to HCPs not deemed to be government officials, pre-approval of the HCP's employer should nevertheless be obtained for the sake of transparency.

### **PReMA Code**

There are no specific requirements for a HCP to obtain a written pre-approval from the HCP's employer to attend an event organized by a pharmaceutical company.

### **MOU on the code of conduct for sales promotion in Thailand**

Under the MOPH Notification, HCPs cannot directly accept sponsorship from a pharmaceutical company to attend a meeting, seminar, training, work presentation or an academic event, whether in Thailand or abroad. Such sponsorship must be received by, and under the name of, medical institutes or MOPH agencies, who will be responsible for selecting the qualified HCP.

Under the NDSDC Guidelines, a HCP may accept sponsorships from a pharmaceutical company to attend an event, conference or seminar.

The sponsorship can only cover travel expenses, registration fees, speaker's fees, as well as food and accommodation allowances for only the attending HCP.

However, such sponsorship must be received under the supervision of the medical institution in which the HCP works.

# Vietnam



## Vietnam

Yee Chung Seck and Minh Ha Vu

### 1. Can a pharmaceutical company provide gifts to a HCP?

Gifts to HCPs, including but not limited to cash, cash equivalents (such as gift vouchers), stocks, goods, valuable papers, entertainment, traveling tours and services, are strictly prohibited.

Furthermore, the gift exception under previous regulations (which applies to gifts with a value of less than VND 500,000 that are given on certain special occasions, e.g., weddings and holidays, such as Tet) is no longer available. As a result, public officials must always disclose gifts received, regardless of the value of the gift, if it was given for an unlawful purpose.

### 2. Is there “transparency legislation” relating to payments by pharmaceutical companies to HCPs?

There is no specific “transparency of payment to healthcare professionals” legislation in Vietnam.

However, there is a regulation that forbids pharmaceutical companies from using material or financial benefits in any form to influence doctors in order to promote the prescription of their products.

As for HCPs, they are prohibited from abusing their prescription activities for personal gains. Furthermore, doctors and management of state hospitals are subject to the regulations on disclosure of private assets and income applicable to state officers in state agencies.

### 3. Can a pharmaceutical company offer giveaways or other gimmicks to a HCP? Is there a specific threshold regulated by law?

“Giveaways” and “gimmicks” are industry terms and not regulated by law.



Vietnamese law does not specify whether a pharmaceutical company can offer giveaways or other gimmicks to a HCP. There is also no specific threshold regulated by law for giveaways or gimmicks.

**4. Can a pharmaceutical company sign a service contract (such as for speaking and chairing at meetings, translating medical documents, writing medical articles and/or giving medical training) with a HCP?**

Yes, provided that the HCP does not give advice and/or consultancy services related to their management duties or state secrets. Under the Public Employee Law, before signing a service contract with a pharmaceutical company, the HCP must obtain pre-approval from the hospital's head.

**5. Are HCPs required by law to obtain written pre-approval from their employers to be able to attend an event organized by a pharmaceutical company?**

HCPs are required to obtain consent from their employer to attend an event. However, the law does not specify whether the consent should be given in writing or verbally. We recommend that written consent should be obtained as this demonstrates that a pharmaceutical company is transparent in its invitation and that there is no bribery or corruption involved.

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