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Taiwan: Trends and Developments

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TAIWAN

Trends and Developments

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Lee, Tsai & Partners Attorneys-at-Law is a full-service boutique local firm servicing the Greater China region and includes around 30 attorneys. Lee, Tsai & Partners' headquarters are in Taipei, co-operating with a local partner law firm in Shanghai and the representative office of a local IP consulting firm in Beijing. The firm's biotech and pharmaceutical law team includes a former judge and experienced attorneys with backgrounds in M&A and biotech, and is led by Dr Chung-Teh Lee. The group's services include but are not limited to providing advice regarding the strategic planning and management of IP rights in relation to the biotech and pharmaceutical industry; providing legal counselling services covering all stages of the biotech and pharmaceutical industries; assisting biotech and pharmaceutical clients in formulating M&A plans; and supporting them on cross-border M&A transactions. The firm's clients includes multinational pharmaceutical research firms, listed medical device and pharmaceutical companies and pharmaceutical manufacturing companies.

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The Pharmaceutical Advertisement Regulatory Structure in Taiwan

Definition of pharmaceutical advertisements

Pharmaceutical advertisement includes advertisement for pharmaceutical products and for medical devices; it refers to acts of promotion of medical efficacy through broadcasting for the purpose of attracting sales (Articles 4 and 24 of the Pharmaceutical Affairs Act). In other words, if an advertisement containing promotion of medical efficacy of a pharmaceutical product can, upon reception by an audience person:

- cause such person to become aware of such product;
- increase the desire of such person to purchase or use such product; and
- further enable such person to be able to obtain such product by the information in the advertisement, thereby achieving a commercial profitable effect,

then such advertisement constitutes "pharmaceutical advertisement" under law.

In practice, advertisement that may include claims of medical efficacy may also include "medical education advertisement" and "food product advertisement". Since, unlike "pharmaceutical advertisements", they do not require regulatory approval before broadcasting, distinguishing the categories is important.

"Medical education advertisements"

These may not involve specific product names, and measures must be taken to clearly separate them from related pharmaceutical advertisements (ie, not broadcasting them back-to-back and not using the same endorser/presenter) to prevent consumer confusion. According to the Ministry of Health and Welfare (MoHW), if medical institutions intend to provide medical education information, they should adequately disclose medical information necessary for the proper use of such drugs, including indications, warnings, side effects, dosage and administration. The MoHW has further indicated that whether the separation from related pharmaceutical advertisements has been adequately made shall be determined by an assessment of the overall contents of the advertisement; if such separation is not clearly made, then pre-broadcast approval will still be required.

As an example of the aforementioned separation, a pharmaceutical company posted advertisements outside brick-and-mortar pharmacies that contained keywords designed to invite the viewer to go to a specific website and conduct certain self-administered health exams. The company called this a "medical education advertisement" because the purpose of the advertisement is to raise public awareness of erectile dysfunction and it did not mention the company or its product by name. However, the court disagreed on grounds that the website in question did not provide any specific explanations on causes of the condition, symptom descriptions or available treatment options, nor did it provide the result of the "self-exam", making the exam itself mostly meaningless to the website visitor; instead, it contained clear links to the company's official website and specific drug products. The court thus deemed the physical advertisements outside pharmacies as "pharmaceutical advertisements" because the keywords were clearly intended to attract people to visit its website to purchase its products rather than to educate.

"Food product advertisements"

These cannot make any claims, promotions or labels of medical efficacy (Article 28 (2) of the Act Governing Food Safety and Sanitation). Any assertions by an advertisement that the advertised food product may prevent, ameliorate, reduce, diagnose or cure diseases will all be deemed as claims of medical efficacy in practice and thus disallowed (Article 5, Subparagraph 1 of the Regulations Governing the Determination of False, Exaggerated or Misleading Labeling, Promotion and Advertising of Foods and Related Products, or Involving Medical Efficacy).

An example of the above is a food product company that claimed in an online advertisement that its product could soothe oral ulcers by preventing or ameliorating inflammations and pain. A court found such advertisement to constitute an unlawful food product advertisement due to how the wording used might create a misleading expectation in the consumer that it could be used to treat such symptoms without needing to obtain proper medical advice from a physician.

The MoHW has also expressly ruled that the following are not considered pharmaceutical advertisements and thus do not need pre-approval before broadcast:

- a posting by a pharmaceutical company on its website of the full contents of the package insert of its own pharmaceutical product that has been approved by the Taiwan Food and Drug Administration (TFDA), along with a picture of the outer packaging or the external appearance of the product;
- any advertisement sponsored by the pharmaceutical company under its name that does not involve the promotion of a specific product or its medical efficacy; and
- any information posted by a pharmaceutical company on its website regarding how to discern genuine pharmaceutical products for strengthening the medical education of physicians, pharmacists and patients who have received a prescription for such products, provided that the pharmaceutical company has disclosed to the MoHW in advance how it would conduct this campaign and obtained the MoHW's approval.

The pre-broadcast approval of pharmaceutical advertisements

Taiwan requires pre-broadcast submission and approval of pharmaceutical advertisements, and the restrictions placed on who can make pharmaceutical advertisements, what they may contain and for how long they may be broadcast are considerable. However, from a constitutional perspective (Judicial Interpretation No.414), laws and regulations that restrict commercial speech such as pharmaceutical advertisements must be balanced against the health and public interest of the people.

Currently, only pharmaceutical companies may make pharmaceutical advertisements (Article 65 of the Pharmaceutical Affairs Act (PAA)). Prior to broadcast, the pharmaceutical company shall submit the complete contents of the advertisement to the MoHW or the local municipal competent authority on health for review and approval; the contents in the actual broadcast should be identical to those submitted for approval (Article 66 of the PAA). In principle, an approved advertisement may be broadcast for one year from the date the approval was issued, but renewals for one year each may be applied for with the same approval authority (Article 66-1 (1) of the PAA).

Restrictions on the contents and promotions in the pharmaceutical advertisements

In conducting its review of a pharmaceutical advertisement, the MoHW will look for content that is inappropriate or prohibited by law. Content that the MoHW will flag includes any statements involving sexual performance, incentives (eg, prizes for trading in the drug packaging) that may create long-term drug dependency, or claims that the drug will cure a particular disease, that the drug will improve a person's constitution, or that otherwise falsify or exaggerate the medical efficacy of the drug (Article 47 of the Enforcement Rules of the PAA). Wording and imagery on the advertisement must conform with the approved name, dose, prescription content, usage method, efficacy, guidelines and packaging of the product; the name of the pharmaceutical company, the drug licence for the product and the advertisement approval document must also be published alongside the advertisement (Articles 45 and 46 of the Enforcement Rules of the PAA). Inappropriate promotional conduct, such as falsely using the name of another company, the citation of medical literature to guarantee efficacy, or the use of interviews or media reports, are all prohibited for pharmaceutical advertisements (Article 68 of the PAA).

Pharmaceutical product endorsement review standards

The Taiwan Fair Trade Commission (TFTC) has published The TFTC Notes on Endorsement Advertisement Regulations ("Endorsement Ad Regulations") to provide guidance on how it regulates endorsements in advertisements in Taiwan, including pharmaceutical advertisements. An "endorsement advertisement" is defined as any advertisement or public-reaching means that expresses to the public opinions, discovery, personal experience and trust with respect to the product or service in question. The person or entity stating the aforementioned opinions in the advertisement regarding the product or service is the endorser. The owner of the advertisement has a duty to ensure that the advertisement accurately reflects the endorser's opinion or personal experience without any falsified or misleading expressions. The advertisement

must fully disclose any interest between the owner of the advertisement and the endorser that the general public cannot reasonably expect to be aware of; in the case of endorsements in social media posts, the endorser also has the same duty of disclosure.

In principle, the competent authority conducting a pre-broadcast review of a pharmaceutical advertisement does not conduct a substantive review of the identity of the endorser, the endorser's recommendation or the contents of the endorser's opinion; the pharmaceutical company is merely asked to comply with the good faith principle in creating the advertisement contents. However, the endorser's opinion on the use of the pharmaceutical product is still regulated by law and the aforementioned Endorsement Ad Regulations. Any joint intentional creation of a misleading advertisement by the endorser and the owner of the advertisement may result in a penalty for the endorser under the same rules in theTaiwan Fair Trade Act for penalising the advertisement owner. In addition, if an endorser knowingly makes a misleading comment or could have known that the contents of the endorsement in the advertisement might mislead the consumer but nevertheless makes the endorsement, the endorser will also be held jointly and severally liable with the owner for damages.

Recent Trends in Pharmaceutical Advertisement Violations

Forms of violations

According to the MoHW's published data on its online public inquiry system regarding "food, pharmaceutical and cosmetic advertisement violations", the forms of pharmaceutical advertisement violations observed for the period from 1 January 2025 to 30 March 2026 include:

1. advertisements by non-pharmaceutical companies;
2. failure to obtain approval in advance before broadcast;
3. inconsistencies between the contents of the advertisement and the approval application;
4. broadcasters publishing or airing pharmaceutical advertisements that have been found as in violation of the law; and
5. claims of medical efficacy for non-pharmaceutical products.

Of the above, points (3) and (5) were the most common.

An example of a (2) violation is when a retail pharmacy posted an advertisement for an approved drug on its website, but the advertisement contained details about the drug as well as comparisons with competing drugs that were not submitted for approval in advance, which resulted in a fine of TWD220,000 imposed by the competent authority. In another very similar case to the above, a well-known retail pharmacy posted advertisements for three of its approved drug products, but they contained claims of medical efficacy that had not been submitted for approval in advance, which again resulted in a fine of TWD240,000 imposed by the competent authority.

An example of a (3) violation is when a retail pharmacy left leaflets depicting an injectable blood sugar control drug at the front desks of clinics for the general public to take. However, when the drug advertisement was approved, the advertisement type was for academic medical publications only, with no authorisation for promotions via leaflets. In addition, the leaflet was found to contain descriptions that implied improvement of body constitution, as well as instructions on how to manage side effects, both of which were not within the scope of the type and content of advertisement previously approved by the competent authority. The fine levied by the competent authority was set at TWD200,000.

An example of a (5) violation is when an entity purchased advertisement space on an e-commerce platform for its topical analgesic patch product, but the advertisement contained language that implied such product could adjust the acid-base balance of the human body and ameliorate several bodily ills. The competent authority determined that this constituted claims of medical efficacy for a non-pharmaceutical product and levied a fine of TWD600,000 as a result.

In addition, according to the TFDA's list of the top ten food product advertisement violations published on 19 March 2025, a large majority of the food product advertisement violations were (5) violations for

improperly asserting medical efficacy for the subject food product. The highest recorded fine involved a food product advertisement that claimed the product could treat sarcopenia, degenerative arthritis, or even reverse muscular atrophy symptoms, which resulted in a fine of over TWD11 million.

Penalty standards and current status

As hinted above, the penalty levied by the competent authority for a pharmaceutical advertisement violation depend on the type of violation found. Taking the aforementioned five common forms of pharmaceutical advertisement violations observed, (1), (2) and (3) violations generally result in a fine between TWD200,000 and TWD5 million (Articles 91 (1) and 92 (4) of the PAA). For consistency in penalty determination, the MoHW has promulgated a circular on the principles of handling violations of Articles 65, 66 and 69 of the PAA (ie, covering the aforementioned "pharmaceutical advertisement violations", hereinafter the "Advertisement Handling Principles"), under which the fine starts with a baseline amount of TWD200,000 for a first violation, with each subsequent additional product or advertisement in violation resulting in a 10% increase over the previous amount. Nevertheless, in practice, the competent authority will consider the severity of impact from the violation, the level of blameworthiness of the persons involved, the amount of profit obtained, etc. as factors in deciding the final amount.

However, a (5) violation is considered a more serious case due to the potentially more deleterious impact on the public, and it may result in a fine between TWD200,000 and TWD25 million. The competent authority may also order the destruction of such products (Article 91 (2) of the PAA). Under the aforementionedAdvertisement Handling Principles, a (5) violation has a starting fine of TWD600,000 for a first offence, which is also further increased for each subsequent product or advertisement found in violation.

In addition to levying a fine on the company involved, the competent authority may also impose administrative sanctions on the violator, including disclosing the company's name, the name of the company's responsible person, the name of the product involved, and a description of the violation found in an advertisement space of a newspaper. A serious violation may even result in the revocation of drug permits issued to the company, as well as an order for the company to make a public apology in the same advertisement space (ie, the same time slot and the same length/size) of the same media that was previously used for the unlawful pharmaceutical advertisement. Failure to comply with such sanctions may result in the suspension of all pharmaceutical advertisements by such company and a permanent blacklist on all future pharmaceutical advertisement approval applications (Article 96 of the PAA).

It should be noted that the Taiwan courts have reached a consensus on whether repeated broadcasts of the same unlawful advertisement constituted a single or multiple acts in law: Advertisement is considered a collective concept. In the case of a (1) violation in which a non-pharmaceutical company repeatedly claims medical efficacy for its product in order to attract sales, if such broadcasts can be deemed as a single intent that violates a specific provision of the PAA, they should still be deemed as a single act under law and thus should only be penalised once. The imposition of a penalty by a competent authority should then constitute a separator for the "unity" of the single legal act afterwards.

Joint liability

"Broadcaster obligations and liabilities"

As indicated in the (4) violation above, broadcasters may be held liable alongside the company behind the product advertisement that violates the aforementioned pharmaceutical advertisement content restrictions. A broadcaster may not broadcast any pharmaceutical advertisement that has not been approved by the competent authority, is inconsistent with the approved contents, has been withdrawn, or has not been timely rectified after it has been ordered to do so (Article 66 (3) of the PAA). Penalties include a fine from the competent authority between TWD200,000 and TWD5 million, as well as an order to suspend broadcast of such advertisement; failure by a broadcaster to suspend broadcast of such advertisement will result in consecutive fines of TWD600,000 to TWD25 million until the order has been complied with (Article 95 (1) of the PAA).

In addition, broadcasters of pharmaceutical advertisements must maintain for up to six months after

broadcast records of the identity of the company that purchased the ad space for such pharmaceutical advertisement to be broadcast, and they must comply with any request from the competent authority to provide such information without refusal or complaint (Article 66 (4) of the PAA). Penalties for violation of such data storage and compliance obligation include a fine between TWD60,000 and TWD300,000, with the possibility of consecutive fines (Article 95 (2) of the PAA).

"Endorser liabilities for improper medical efficacy claims"

As mentioned above, individuals who participate in unlawful pharmaceutical advertisements by making an endorsement of the subject product may be jointly penalised alongside the owner for the unlawful advertisement. In the aforementioned largest (5) violation case involving false claims of the food product being able to treat sarcopenia, degenerative arthritis and muscular atrophy, the public personality involved in endorsing that food product was also fined for a total of TWD2.16 million.

In light of a growing number of fines imposed on celebrities/personalities due to their product endorsements for unlawful pharmaceutical advertisements, the MoHW and the TFTC have issued advisories to medical or pharmaceutical personnel to comply with the Endorsement Ad Regulations and avoid participating in unlawful pharmaceutical advertisements or implying exaggerated medical efficacies of the product involved.

Recent Trends in Pharmaceutical Advertisement Regulatory Efforts

With the continued introduction of new types of drugs into Taiwan, as well as the difficulty in regulating the manifold forms of promotional activity in today's media, the MoHW has, besides increasing its vigilance regarding pharmaceutical advertisements, started involving private businesses to assist in enforcement. Taking the recent growing popularity of GLP-1 weight-loss drugs as an example, due to the widespread unlawful advertisements and sales of such products online, the TFDA has, in addition to working with local health authorities in conducting inspections and audits, established mechanisms to cause such advertisements and sales to be removed from online platforms. This included working with *Meta* to take down unlawful posts, with the Taiwan Network Information Center to establish means to block web domains containing unlawful content, and with pharmacists' associations to strengthen online investigation efforts.

This year, the TFDA has announced efforts to propose an amendment of the PAA that would strengthen regulation of online sales of pharmaceutical products by stipulating concrete rules and proper allocation of responsibilities. Some of the possible amendments include the immediate removal of such unlawful information online upon notification to the competent authority, and working with telecommunications entities on active blocking of web domains.

Regenerative treatment, such as exosome therapy, has also become a recent hot topic in pharmaceutical advertisements. Even though the Regenerative Medicine Act and the Regenerative Medical Products Act formally went into effect in Taiwan on 1 January 2026, entities looking to advertise products based on regenerative medicine must still abide by the old regime under the PAA. For exosome therapy, this meant having to obtain an approval for its regenerative medicine therapy plan to conduct exosome therapy from the MoHW before any such advertisement may be broadcast. As of the time of this writing, the MoHW has yet to approve any application for broadcasting exosome therapy advertisements. As a result, all online advertisements involving exosome therapy that existed in recent years are in fact still unlawful and may be penalised under law. Accordingly, regenerative medicine advertisements have also become a key target of the MoHW's strengthened inspection efforts.

In response to the strengthened inspection and audit efforts from the MoHW and local competent authorities on health, pharmaceutical companies are advised to focus on understanding the relevant regulations and review standards very early in the pharmaceutical advertisement planning phase so as to avoid setbacks to their business in the Taiwan market caused by a failure in obtaining the prerequisite pre-broadcast approval, or post-broadcast administrative sanctions such as fines or orders to take such advertisements off the air, due to unfamiliarity with the relevant rules.

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