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Promoting Medical Products Globally

Handbook of Pharma and MedTech Compliance

TAIWAN

Taiwan

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Introduction

In Taiwan, advertising/promoting of medical products, including drugs and medical devices for human use, is simultaneously governed by state legislation and professional codes of practice. The regulators, at the national government level, primarily include the Taiwan Food and Drug Administration (TFDA) and the Fair Trade Commission (FTC); and at the local government level, the Department of Health of city or country government (Local DOH). Medical product advertising applications are reviewed by the TFDA or municipal competent health authority, and illegal advertising is monitored and sanctioned by the Local DOH. False or misleading advertising and unfair competition due to promoting of medical products are supervised and sanctioned by the FTC.

Regulatory Framework

Advertising of Medical Products

Advertising of medical products in Taiwan is primarily governed by the Pharmaceutical Affairs Act (PAA), last amended in 2013. Under the PAA, "advertising of medical products" refers to the act of advertising the medical efficacy of medical products by means of communication aiming to solicit and promote the sale of advertised products. Interviews, news reports or propaganda containing information implying or suggesting medical efficacy of a product for human use are also regarded as advertisements of medical products.

The PAA provides that a prior approval for medical product advertising from the TFDA or municipal competent health authority is required. All text, images and phrases of product advertisements must be reviewed and approved by the regulator before the advertisements become public. Marketing approval is required to advertise medical products. The approval for advertising is valid for one year,

extendable for another year if the advertiser submits an extension application.

In addition to PAA, the general provisions of the Consumer Protection Act (CPA), last amended in 2015 and the Fair Trade Law (FTA), last amended in 2015; the anti-trust law of Taiwan must also be taken into account when advertising medical products. The CPA generally requires that advertisers must ensure the accuracy of the contents of their advertisements and are obligated to uphold the promises made to the consumers in such advertisements.

The FTA prohibits false or misleading advertisements. Under the FTA, no enterprise may make or use false or misleading representations or symbols as to price, quantity, quality, content, production process, production date, validity period, method of use, purpose of use, place of origin, manufacturer, place of manufacturing, processor, or place of processing of goods or in advertisements, or in any other way making known to the public.

Anti-Unfair Competition

Other than advertisements, the PAA does not say much on promotion of medical products. Product promotional activities targeting healthcare professionals are mainly governed by anti-unfair competition legislation and anti-bribery legislation.

Illegal advertising of medical products, for example, comparative advertising, may constitute unfair competition under the FTA. According to the FTA, no enterprise may, for the purpose of competition, make or disseminate any false statement that may damage the business reputation of another.

Unethical promotional activities, such as offering improper gifts, entertainments, hospitality, sponsorship, and other interests to healthcare professionals/institutions for the purpose of promotion of medical products, may also raise concerns of unfair competition. Pursuant to the FTA, no enterprise, including pharmaceutical and medical device companies, may cause the trading counterparts of its competitors to do business with itself by coercion, inducement with

interest, or other improper means, which is likely to lessen competition or to impede fair competition. The FTA also prohibits any enterprise from deceptive or obviously unfair conduct that may affect trading order.

Bribery

The Anti-Corruption Act (ACA), last amended in 2011 prohibits any person (e.g., representatives of a pharmaceutical or medical device company) from bribing or unjustly enriching public officials (e.g., public hospital's healthcare professionals who have legal authority in accordance with law). The provider and taker of bribes will face criminal liability if he/she is found guilty of bribery under the Anti-Corruption Act.

The Criminal Code prohibits private parties' employees (e.g., healthcare professionals employed by private hospitals) from illegally receiving bribes or other improper benefits in breach of their work duties. A briber is deemed an accomplice of the person being bribed and may be subject to criminal penalty.

Public Procurement

The Government Procurement Act (GPA), last amended in 2011 aims to establish a fair and open government procurement system and punishes some offenses which encroach the fairness of government procurement. This Act is also applicable to the procurement process of public hospitals. Therefore, medical products purchased by public hospitals are subject to the tendering rules under the GPA.

Permitted and Prohibited Practices - Advertisements

Types of Media Permitted for Medical Product Advertising

An advertiser may advertise its medical products on TV, radio, newspapers, websites or by email, posters, etc. However, if the product to be advertised is a prescription-only medical product, it can only be advertised in scholarly medical publications or on websites to which only healthcare professionals have access.

Advertising to End-Consumers/Patients

Advertising non-prescription medical products to consumers is permitted. Conversely, advertising prescription-only medical products to consumers is not permitted. As mentioned, advertisements of such products can be published in academic medical journals or on websites to which only healthcare professionals may have access.

Prohibited Forms of Medical Product Advertising

Medical product companies are prohibited from running advertising campaigns that use:

- a third-party name in the advisement without his/her consent
- information published in books or journals to guarantee the effects and functions of the products
- interviews or reports to promote the products
- other inappropriate methods

Prohibited Advertising Claims

Medical product advertisements may not:

- Mention or suggest sexual function
- Offer incentives which may encourage misuse of medical products
- Fabricate the information used in the advertisement
- Exaggerate the medical effectiveness or safety of the product.

Advertising of Company Name

Advertising the name of a pharmaceutical or medical device company without mentioning any product information does not amount to "medical product advertising" under the PAA. Prior regulatory approval is therefore not required.

Off-Label Use Advertising

Advertising of medical products can only refer to the indications which have been approved by the TFDA in the marketing approval of the advertised product. Advertising of off-label use is a violation of PAA.

Advertising of Product Name

Conversely, advertising the name of a medical product is likely to be regarded by regulators as "medical product advertising" under the PAA and prior regulatory approval for advertising may be required, even though no "medical effectiveness of the pharmaceutical product" is claimed in the advertisement.

Product Information Company's Website

Regulatory approval is not required for the "product information" disclosed on the website of the holder of marketing approval of medical products.

According to the TFDA's regulations, such "product information" must include, and is limited to, the name and photos or package of the product, and the entire contents of user instruction of the product which have been approved by the TFDA.

Advertising of Price

Advertising the price of a medical product is permitted in Taiwan. However, if there are any incentives advertised, e.g., discounts, which are likely to encourage abuse of medical products, the regulatory approval for such advertising will not be granted.

Promotion by Means of Gifts or Prizes

Promoting medical products by offering gifts or prizes to consumers is likely to encourage abuse of the medical products and therefore is not permitted in practice.

Comparative Advertising

Comparative advertising is not expressly prohibited under Taiwan law. However, in practice the application of comparative advertisement would not be approved by any health authority as, if such approval is granted, the health authority may be deemed to guarantee to the consumers that the product to be advertised is better than the product to be compared.

Testimonial Advertisement

Testimonial advertisement for medical products is permitted in Taiwan. An endorser can be a celebrity, a medical professional, or a consumer. The contents of the advertisement must truly reflect the endorser's comments on the advertised products. The endorser will be jointly and severally liable with the advertiser if he/she knows or should have known that his/her endorsement is likely to mislead the public.

Supply of Scientific Data and Literature

Normally, the supply of scientific data and literature relating to medical products to healthcare professionals by the pharmaceutical or medical device company is not considered advertising. However, if the scientific data and literature imply or suggest the effect of a specific medical product, or even include the name of the medical product suppler, they may be treated as product advertising under the PAA and will thus be subject to supervision by the regulators.

Patient Information Sessions

Some players in the industry believe that information session for patients or doctors does not constitute "medical product advertising" under the PAA if the information session is provided for specific persons only, and not the public. But according to the TFDA, the information session is also likely determined as "medical product advertising," which requires prior approval from the regulator, if the products are promoted there with a purpose to generate sales of the products.

Consequences of Breach

Liabilities for Illegal Advertising of Medical Products

Liability Under the Pharmaceutical Affairs Act

The liabilities for infringement of the advertising legislation under the PAA mainly include the following:

- A fine of up to TWD25 million
- Publication of the violation, the name of the advertiser's responsible person, and the name of advertised product in the newspaper by the regulator
- Revocation of the marketing approval of the advertised product
- Publication of an apology in the media by the advertiser
- Suspension of use of the name of the advertised product for two years

Liability Under the Consumer Protection Act

If a pharmaceutical or medical device company violates the advertiser's responsibility for the accuracy of the contents of its advertisements for a medical product under the CPA and therefore causes damage to the consumer(s), it will be liable for the damage the consumer(s) suffered. In addition, the advertising medium will be jointly and severally liable with the advertiser if it knows or should have known that the contents of advertisements are inconsistent with the facts.

Liability Under the Fair Trade Act

If an advertisement for a medical product is determined by the regulator as false or misleading advertisement under the FTA, the advertiser will be imposed a fine of up to TWD25 million. The advertising agency, the advertising medium and/or the endorser will

be jointly and severally liable with the advertiser if they know or should have known the advertisement is likely to mislead the public.

Unfair Competition

If illegal advertising of medical products, for example, false or misleading advertisements, is determined by the regulator to have damaged the business reputation of the competitor, the infringer will be punished by imprisonment for up to two years and/or a fine of up to TWD50 million.

Professional Codes of Conduct

Guidelines Governing the Relationships Between Physicians and Vendors

The Ministry of Health and Welfare promulgated in 2006 the Guidelines Governing the Relationships between Physicians and Vendors (MOHW Guidelines) which set forth the principles for physicians on accepting gifts, participating in professional meetings and conducting research sponsored by the vendors (e.g., pharmaceutical or medical device companies), and for the physicians' provision of consulting services to vendors.

Gifts

When receiving a gift from a vendor, a physician must follow the rules below:

- Do not violate any laws or any policies established by a national medical society or association.
- Conform with local practice and accept only inexpensive gifts.
- Do not accept money, gift vouchers equivalent to cash, or securities.
- Do not agree or imply use of any specific medical product, or refer any patient to any specific facility based on the gift received.

Sponsorship

With respect to physicians' participation in professional meetings sponsored by the vendors, the MOHW Guidelines provide certain standards, as follows:

- Professional meetings should be for the purpose of promoting quality healthcare, benefiting patients and exchanging useful and up-to-date information about the medical profession. Academic discussion time must comprise at least two-thirds of the total time of the meeting.
- Physicians are allowed to accept only certain grants covering expenses for travel and meals, and registration fees. They may also accept remuneration if they have been invited to deliver lectures or act as moderators in professional meetings.
- Organizers of professional meetings must announce the names of sponsors and duly inform participants about the relationship between the sponsor and organizer, lecturers or moderator.
- Physicians must present their works or materials at professional meetings in accordance with scientific practice without being affected or having to be pressured by vendors, and provide a balanced opinion on alternative treatments.
- Organizers should reject vendors' uncalled-for intervention in the content of professional meetings, manner of publication and the choice of lecturers.

On research sponsored by vendors, the MOHW Guidelines also set forth certain standards, as follows:

- The performance of any research work and the publication of the results of such research should be in compliance with applicable laws, ethical rules and the Declaration of Helsinki, and adhere to professional judgment.

- The remuneration for conducting the research should be based on the time and effort a physician has spent but not the conclusion of the research.
- The name of the sponsor must be announced when the research results are published.
- The vendor must not impose improper restrictions on the publication of research results.

Consulting Services

When acting as the consultant of a supplier or providing advice to a vendor, a physician must not:

- Give any professional determination compromised by the fact that he/she acts as the consultant of a vendor or provides advice to a vendor.
- Be negligent of his or her obligations to a patient due to his or her acting as the consultant of a vendor or providing advice to a vendor.
- Disclose his or her affiliation or other relationship with the vendor when making a speech, or publishing an article or report.

Code of Conduct for Government Officials

The Code of Conduct for Public Officials promulgated by the Executive Yuan (last amended in 2010) applies to healthcare professionals employed by state-owned hospitals.

Gifts

The Code of Conduct for Public Officials provides that a public official may not demand, solicit or accept gifts from persons who are in a conflict of interest with his or her official duties. However, where any of the following applies, and where it is an occasional event unlikely to affect specific rights and obligations, the gift may be accepted if:

- It is part of official etiquette.
- It is a reward, assistance or condolence gift from a supervisor.
- The market value of the gift is under TWD500; or where it is a gift to the majority of the authority (institution), total market value is under TWD1,000.
- Gift is received for an engagement, marriage, birth, relocation, employment, promotion or reassignment, retirement, resignation, termination of employment, or sickness, injury or death of the individual, his or her spouse or a direct relative, provided that the market value of such gift does not exceed the usual standard of social etiquette.

The aforesaid "usual standard for social etiquette" means that the market value of the social interactions does not exceed TWD3,000, and gifts or hospitality received from the same source within one year do not exceed TWD10,000.

Note that the following are deemed to be gifts to a public official:

- Gifts received in the name of the public official's spouse, direct blood relative, or cohabiting relative
- Gifts received by a third party, and then redirected to the public official or the public official's spouse, direct blood relative, or cohabiting relative

Hospitality

Public officials may not attend entertainment and hospitality events hosted by persons in a conflict of interest with such official. Nevertheless, the following exceptions apply:

- It is necessary to attend such event due to official etiquette.
- It is a public event hosted for folk customs or festival reasons, and the general public is invited.

- It is a reward or encouragement given by a supervisor to a subordinate.
- It is an event hosted for an engagement, marriage, birth, relocation, employment, promotion or re-assignment, retirement, resignation or termination of employment, provided that the value of entertainment and hospitality does not exceed the usual standard of social etiquette.

Public officials should avoid attending entertainment and hospitality events that are clearly disproportionate with their status and duties, notwithstanding the host has no conflict of interest with their duties.

A public official must not appear in inappropriate locations, except as required for official duties and having been approved by the supervisor, or for other legitimate reasons. Public officials must not have improper contact with persons whose duties may pose a conflict of interest.

While conducting an inspection, investigation, a business trip or attending a meeting, the public official may not accept dining or other hospitality from relevant authorities (institutions) other than snacks and/or plain and convenient food, accommodation and transportation required for carrying out official duties.

Speeches, Conferences, Seminars and Adjudications

The pay for a public official to attend speeches, conferences, seminars and adjudications must not exceed TWD5,000 per hour. Where a writer's fee is paid for attending an above event, the fee must not exceed TWD2,000 per 1,000 words.

Where an above event is organized by a person with a conflict of interest with the public official's duties, the public official must first apply for approval from his or her supervisor and register with the relevant ethics department before attending.

IRPMA Code of Practice

The ROC International Research-Based Pharmaceutical Manufacturers Association (IRPMA) promulgated Code of Practice (IRPMA Code), last amended in 2012 which sets forth standards for the ethical promotion of pharmaceutical products to healthcare professionals, and for member companies' interactions with them.

Under the IRPMA Code, a "healthcare professional" means "any member of the medical, dental, pharmacy or nursing professions or any other person who in the course of his or her professional activities may prescribe, recommend, purchase, supply, or administer a pharmaceutical product." Member companies of IRPMA include drug and medical product manufacturers as well as their distributors and agents.

The IRPMA Code does not seek to regulate the promotion of non-prescription pharmaceutical products, pricing or other trade terms for the supply of pharmaceutical products, the engagement of a healthcare professional to provide genuine consultancy or other genuine services to a member company, the conduct of clinical trials, or the provision of non-promotional information by member companies.

The IRPMA Code provides the following principles:

- Basis of Interaction: Member companies' relationships with healthcare professionals are intended to benefit patients and to enhance the practice of medicine. Interactions should be focused on informing healthcare professionals about products, providing scientific and educational information, and supporting medical research and education.
- Independence of Healthcare Professionals: 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 healthcare professional 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 have an inappropriate influence on a healthcare professional's prescribing practices.

- Appropriate Use: Promotion should encourage the appropriate use of pharmaceutical products by presenting them objectively and without exaggerating their properties.

- Local Regulations: In all cases, all relevant laws, local regulations and industry codes must be observed and companies have a responsibility to check local requirements, in advance of preparing promotional materials or events in any specific country.

- Transparency of Promotion: Promotion should not be disguised. Clinical assessments, post-marketing surveillance, and experience programs and post-authorization studies must not be disguised promotion. Such assessments, programs and studies must be conducted with a primarily scientific or educational purpose. Materials relating to pharmaceutical products and their uses, whether promotional in nature or not, which are sponsored by a company should clearly indicate by whom it has been sponsored.

Events

Scientific and Educational Objectives: The purpose and focus of all symposia, congresses and other promotional, scientific or professional meetings ("Event") for healthcare professionals organized or sponsored by a company should be to inform healthcare professionals about products, and/or to provide scientific or educational information.

Events Involving Foreign Travel: No company may organize or sponsor an event for healthcare professionals that takes place outside of their home country unless it is appropriate and justified to do so from a logistical or security point of view. International scientific

congresses and symposia that involve participants from many countries are therefore justified and permitted.

Promotional Information at Events: Promotional information which appears on exhibition stands or is distributed to participants at international scientific congresses and symposia may refer to pharmaceutical products which are not registered in the country where the event takes place, or which are registered under different conditions, provided that the following conditions are observed:

- Host country regulations should permit such an arrangement;
- The meeting should be a truly international, scientific event with a significant proportion of the speakers and attendees from countries other than the country where the event takes place.
- Promotional materials (excluding promotional aids) for a pharmaceutical product not registered in the country of the event should be accompanied by a suitable statement indicating the countries in which the product is registered and make clear that such product is not available locally.
- Promotional materials which refer to the prescribing information (indications, warnings, etc.) authorized in a country or countries other than that in which the event takes place but where the product is also registered, should be accompanied by an explanatory statement indicating that registration conditions differ internationally.
- An explanatory statement should identify the countries in which the product is registered and make it clear that it is not available locally.
- All Events should be held in an appropriate venue that is conducive to the scientific or educational objectives and the

purpose of the Event or meeting. Companies must avoid using renowned or extravagant venues.

Sponsorship

Member companies may sponsor healthcare professionals to attend events provided such sponsorship is in accordance with the following requirements:

- The event complies with the hospitality requirements of the IRPMA Code.
- Sponsorship of healthcare professionals is limited to the payment of travel, meals, accommodation and registration fees.
- No payments are made to compensate healthcare professionals for time spent in attending the event.
- Any sponsorship provided to individual healthcare professionals must not be conditional upon an obligation to prescribe, recommend or promote any pharmaceutical product.
- Companies should not pay any costs associated with individuals accompanying invited healthcare professionals.

Payments for Speakers and Presenters

Payments of reasonable fees and reimbursement of out-of-pocket expenses, including travel and accommodation, may be provided to healthcare professionals who are providing genuine services as speakers or presenters on the basis of a written contract with the company at the event.

Hospitality

Limits of Hospitality: Hospitality should be limited to refreshments and/or meals incidental to the main purpose of the event and should only be provided: to participants of the event and not their guests; and if it is moderate and reasonable as judged by local standards.

As a general rule, the hospitality provided should not exceed what healthcare professional recipients would normally be prepared to pay for themselves.

Entertainment: No entertainment or other leisure or social activities should be provided or paid for by member companies.

Gifts and Items of Medical Utility

Prohibition of Cash & Personal Gifts: Payments in cash or cash equivalent (such as gift certificate) must not be offered to healthcare professionals. Gift for the personal benefit of healthcare professionals (such as sporting or entertaining tickets, electronic items, etc.) must not be provided or offered.

Promotional Aids: Promotional aids of minimal value and quantity may be provided or offered to healthcare professionals if relevant to the practice of the healthcare professional. The value of the gift should not exceed TWD500. The names of companies and/or products must be printed on the gifts.

Items of Medical Utility: Medical journal or textbooks for academic use can only be offered to individual hospital departments. Other items of medical utility with modest value may be offered to hospital or clinics if such items do not offset routine business practices and are beneficial to enhancing the provision of medical services and for patient care.

Cultural Courtesy Gifts: Cultural courtesy gifts are not allowed, including but not limited to, gifts offered to healthcare professionals on traditional festivals or flowers and funeral scrolls for funeral.

Samples

Permitted Samples: In accordance with local laws and regulations, free samples of a pharmaceutical product may be supplied to healthcare professionals in order to enhance patient care. Samples

should be marked as such so that they cannot be resold or otherwise misused.

Control and Accountability: Companies should have adequate systems of control and accountability for samples provided to healthcare professionals, including how to look after such samples while they are in possession of medical representatives. Companies should not collect clinical data and should not make any payment to physicians.

Administrative, Criminal and Civil Liability

Liabilities for Unfair Competition

If the promotional activities conducted by a pharmaceutical or medical device company, such as offering improper gifts to healthcare professionals for the purpose of promoting a specific medical product, are determined by the regulator or court as "unfair competition" under the FTA, the violator will be imposed a fine of up to TWD50 million and must rectify the violation within a specific time limit. If the violation is continued after the time limit, the violator may be imposed an additional fine continuously and may, in extreme cases, be punished with imprisonment of up to two years and/or a criminal fine of up to TWD50 million.

Liabilities for Violation of the Anti-Corruption Act

The liabilities applicable to violation of the ACA include the following:

- The provider of bribes for a public official's action breaching official duties will face imprisonment of up to seven years and a fine of up to TWD3 million. The public official receiving such bribes is subject to imprisonment for life or at least 10 years and/or a fine of up to TWD100 million.
- The provider of bribes for a civil servant's action not breaching official duties will face imprisonment of up to three years and/or a fine of up to TWD500,000. The public official receiving such bribes is subject to imprisonment for at least seven years and/or a fine of up to TWD60 million.

Liabilities for Breach of Fiduciary Duty Under the Criminal Code

As mentioned, the provider of bribes to private parties' employees is deemed an accomplice of the person being bribed and may be subject to the same penalty, which is imprisonment of up to five years and/or a fine of up to TWD500,000.

Public Procurement and Fraud

Medical products purchased by public hospitals are subject to the tendering rules under the GPA. In the process of bidding for the government tenders, the following acts will likely be deemed as violation of the GPA:

- Inappropriate contact with or improper influence on government officials during tender opening and tender evaluation period
- Breach of procurement confidentiality
- Use of forceful means to cause a bidder not to tender or to tender contrary to its true intention, or cause the winning bidder to forego or to assign or subcontract an award
- Use of fraudulent or other illegal means to make a bidder unable to tender or cause the opening of tenders to have an inaccurate result
- Cause the bidder not to tender or not to proceed with price competition through contract, agreement or other meeting of the minds with the intent to adversely affect the price of award or benefits

Punishment for breach of the GPA includes imprisonment of up to seven years and a fine of up to TWD60 million.

Contracts with Healthcare Professionals and Medical Institutions

There are no express laws or regulations that specifically govern contracts with healthcare professionals and medical institutions.

According to the IRPMA Code, medical product companies may engage healthcare professionals for speaking arrangements if the speeches are genuine, and written contracts for the speeches are in place. As to other services, the IRPMA Code is silent, but the aforesaid provisions likely remain applicable.

Recommendations

Advertising/promotion of medical products involves legal risks including administrative sanctions, civil liabilities, and criminal penalties. Medical product companies must act very prudently in order to lower their legal risks. We recommend that medical companies pay very close attention to the following items:

- Offering gifts, entertainment or hospitality, and donation or provision of sponsorship may be deemed as a form of bribery under certain circumstances.
- Any benefit provided to the procurement evaluation committee members of public hospitals must be avoided or it may be deemed as a bribe under the ACA.
- Providers and takers of bribes may both be punished by the Anti-Corruption Act or the Criminal Code. Bribery via a third party is also considered as bribery.
- The purpose of the symposium sponsored by the medical product company must be academic or professional. The choice of the venue of symposium may not be on the basis of leisure or entertainment. If most attendants are from Taiwan, an overseas venue for a symposium should be avoided unless there is a strong and sufficient reason.

- Illegal advertising of medical products is not only a violation of advertising legislation, but also probably causes concerns of unfair competition under the FTA. Therefore, the advertiser must avoid using any advertising method which may put its competitors in an unfair position.

This third edition of "Promoting Medical Products Globally. Handbook of Pharma and MedTech Compliance" is intended to provide an overview of the applicable compliance laws governing the cooperation between the medical industry and physicians in Europe, North America, Latin America and the Asia Pacific region. It highlights the legal framework within which medical device and pharmaceutical companies cooperate with health care professionals. It deals with common sponsoring practices such as invitations, conferences and financial grants for research, personnel and equipment as well as other promotional activities such as the giving of gifts, samples and other items and services which are of interest to health professionals. We trust that the third edition is a useful resource for lawyers, compliance officers, managing directors and managers in marketing and medical departments of the medical industry to assess the legal impact on their promotion and marketing activities involving healthcare professionals or medical institutions.

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