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Pharmaceutical Advertising

Japan: Trends & Developments

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2021

Trends and Developments

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Analysis of the Administrative Monetary Penalty and Administrative Order Systems targeting False or Exaggerated Advertising under the PMDA

At a plenary session on 27 November 2019, the House of Councillors passed an amendment to the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (PMDA), which was promulgated on 4 December 2019. The draft amendment includes administrative monetary penalty and administrative order systems to address false or exaggerated advertising of pharmaceuticals and medical devices. The systems will be implemented on 1 August 2021.

This article outlines the newly introduced administrative monetary penalty and administrative order systems under the PMDA, and provides commentary on the differences between these systems and a similar system under the Act against Unjustifiable Premiums and Misleading Representations (UPMR) relating to misleading representations.

Outline of the Administrative Monetary Penalty System under the PMDA

Subject acts

The PMDA imposes a monetary penalty for acts constituting false or exaggerated advertising relating to pharmaceuticals, medical devices, quasi-pharmaceuticals, cosmetics and regenerative medicines (Article 66, Paragraph 1). During the legislature's discussions regarding the amendment to the PMDA, advertising of unapproved pharmaceuticals, medical devices and regenerative medicines (Article 68) was excluded as a basis for the new monetary penalty.

Article 66, Paragraph 1 (Prohibition against False or Exaggerated Advertising)
"No person must, explicitly or implicitly, advertise, describe or circulate false or exaggerated statements regarding the name, manufacturing process, efficacy and effects or performance of pharmaceuticals, quasi-pharmaceuticals, cosmetics, medical devices or regenerative medicines."

Article 68 (Prohibition against the Advertising of Unapproved Pharmaceuticals, etc)
"No person may advertise the name, manufacturing process, efficacy, effects or performance of pharmaceuticals or medical devices, or regenerative medicines… [omitted]… which have not yet been approved… [omitted]…, or which have not yet been certified … [omitted]…"

Scope of false or exaggerated advertising

Only statements regarding the name, manufacturing process, efficacy, effects or performance of pharmaceuticals, etc, may be the basis for a claim of false or exaggerated advertising. False or exaggerated advertising relating to trade terms, such as price or campaign period for pharmaceuticals, is not actionable.

Basis for calculating the monetary penalty

The amount of the monetary penalty is 4.5% of the sales of the subject products for a maximum period of three years.

Exclusion from application of the monetary penalty

If the amount of the monetary penalty is less than JPY2.25 million, ie, if the product sales are less than JPY50 million, the monetary penalty will not be imposed.

Further, a person who becomes subject to an administrative action, such as an administrative order, business suspension order or rescission of business licence, may be exempt from the application of a monetary penalty at the discretion of the Minister of Health, Labour and Welfare.

Reduction of monetary penalties

If a business operator voluntarily reports potential violations of the PMDA prior to commencement of a governmental investigation against it, the amount of the monetary penalty will be reduced by 50%. Further, if an order for payment of a monetary penalty pursuant to the UPMR cumulatively applies, then 3% of the sales, which is the monetary penalty under the UPMR, will be deducted from the monetary penalty under the PMDA.

The authority to issue orders

The Minister of Health, Labour and Welfare has the authority to issue an order for a monetary penalty.

Newly Introduced Administrative Order System under the PMDA

The amendment to the PMDA also introduced a system for administrative orders. Prior to the amendment, only violation of the prohibition against the advertising of unapproved pharmaceuticals, etc, (Article 68) would be the basis for a cease and desist order pursuant to Article 72-5. As a result of the amendment, acts in violation of the prohibition against false or exaggerated advertising (Article 66, Paragraph 1) may be the basis of an order requiring implementation of measures to prevent recurrence of those false or exaggerated advertisements

and public announcements related to implementation of those measures, as well as suspension of the violations.

The title of the provision was changed from "Cease and Desist Orders" to "Administrative Orders concerning Violating Advertisements." The Minister of Health, Labour and Welfare, as well as prefectural governors, has authority to issue administrative orders.

Comparison with the UPMR

Acts that form the basis for monetary penalties

The PDMA authorises a monetary penalty for advertising, describing or circulating false or exaggerated statements concerning the name, manufacturing process, efficacy, effects or performance of pharmaceuticals, etc (Article 66, Paragraph 1).

Similarly, the UPMR imposes a monetary penalty based on representations that mislead people into believing that the quality, standard or any other particulars relating to the content of goods or services are significantly superior to those of the actual goods or services or to those of other business operators (ie, misleading representation of superiority), and representations that mislead people into believing that the price or any other trade terms relating to goods or services are significantly more advantageous than those of the actual goods or services or than those of other business operators (ie, misleading representation of trade terms).

There is some overlap between false or exaggerated advertising under the PMDA and misleading representations of superiority under the UPMR. The PMDA applies to false or exaggerated advertising concerning "the name, manufacturing process, efficacy, effects or performance" of pharmaceuticals, etc, but not to statements concerning the "standard" of a product. Application of the UPMR is not limited to pharmaceuticals, etc, and applies to representations concerning "the quality, standard or any other particular relating to the content" of goods and services in general. Although these criteria are not identical, a false or exaggerated advertisement concerning the standard of a product would also likely constitute a false or exaggerated advertisement concerning its efficacy, effects or performance. Thus, there is significant overlap in the types of statements regarding pharmaceuticals, etc, that would be the basis for monetary penalties under both the PMDA and the UPMR.

However, false or exaggerated advertising concerning trade terms, including price or campaign period for drugs, is not actionable under the PMDA. Therefore, if, for example, a false or exaggerated advertisement regarding price or campaign period of an OTC drug is placed on the internet, the UPMR, rather than the PMDA, would apply.

Persons subject to monetary penalties

The language of Article 66 of the PMDA indicates that there is a possibility that advertising agencies and the media may also become subject to a monetary penalty. By contrast, the UPMR prohibits misleading representations "in connection with the transaction of goods or services that the business operator supplies" (Article 5). Thus, only providers of goods and services (ie, advertisers) may be subject to a monetary penalty under the UPMR.

Calculation of monetary penalties

Both the PMDA and the UPMR provide a maximum sales period of three years as the basis for calculation of monetary penalties.

However, while the monetary penalty under the UPMR is calculated at 3% of the sales of the subject goods or services, the monetary penalty under the PMDA is calculated at a higher ratio of 4.5% of the sales of the subject goods.

Exclusion from imposition of monetary penalties

Exclusion based on sales

The PMDA provides that if the amount of the monetary penalty is less than JPY2.25 million (ie, if sales from the relevant period are less than JPY50 million), then the violator would not be subject to the monetary penalty. The monetary penalty system under the UPMR contains a similar restriction for sales of less than JPY50 million. The minimum penalty amount is set from the perspective of efficient execution of administrative authorities.

Discretionary exclusion based on imposition of other administrative action

The monetary penalty system under the PMDA allows the Minister of Health, Labour and Welfare to exercise discretion not to issue an order for payment of a monetary penalty in the following cases:

- if a business improvement order or an administrative order is issued in a case involving only a minor impact on public health; or
- if a business licence, such as a licence for distribution of pharmaceuticals, is rescinded or a business suspension order is issued in respect of the business operator.

The UPMR does not provide for discretionary exclusion.

However, as a practical matter, if an advertisement is so false or exaggerated as to be the basis for an administrative action, such as an administrative order or the rescission of a business licence, the Minister of Health, Labour and Welfare would be

unlikely to exercise their discretion not to issue an order for a monetary penalty.

Basis for exclusion that is not included in the PMDA
The UPMR provides that a monetary penalty may not be imposed if the business operator "did not fail to exercise due caution about its lack of awareness" of the false representation (Article 8, Paragraph 1). By contrast, the PMDA does not contain a similar provision.

Provision on reduction of monetary penalties
Reduction based on self-reporting
The PMDA states that if a business operator voluntarily reports its potential violations prior to commencement of an investigation, the penalty amount will be reduced by 50%. The UPMR contains a similar provision.

Reduction based on cumulative application of the UPMR
The PMDA further provides that the amount of the monetary penalty will be reduced by 3% in the following cases:

- if an order for a monetary penalty is issued under the UPMR; or
- if an order for a monetary penalty is not issued in accordance with the provision regarding reduction based on the refund policy under the UPMR.

This provision is based on the premise that the systems for monetary penalties under the UPMR and the PMDA are cumulatively applied. Reference to the interpretation of this provision by the Ministry of Health, Labour and Welfare is necessary to determine whether this provision applies even if an order is issued based on the assertion that the representation is a misleading representation of trade terms, rather than a misleading representation of superiority.

Reduction provision that is not included in the PMDA
The UPMR states that the amount of any refund to consumers will be deducted from the amount of the monetary penalty (Article 10). This provision was not included in the PMDA because the UPMR applies to false representations to general consumers and encourages issuance of refunds to compensate consumers for their damages. Since the PMDA applies not only to general consumers, but also to medical businesses or health care professionals, there is little reason to encourage a refund policy.

Shift in the Burden of Proof from the Administrative Authority to Business Operators
The UPMR places the burden of proof of the advertised efficacy and effect on the business operator that made the representation. A representation will be deemed or presumed to constitute a misleading representation of superiority if the business operator fails to submit data to support a reasonable basis for the representation within a designated period (*fujisshou koukoku kisei*) (Article 7, Paragraph 2 and Article 8, Paragraph 3). By contrast, the PMDA does not contain a similar system. Thus, pursuant to the PMDA, the administrative authority must prove "that the advertised efficacy and effect are false or exaggerated."

Violation of Article 68 is Not a Basis for a Monetary Penalty
Only false or exaggerated advertising may be the basis for a monetary penalty. Violation of the prohibition against advertising of unapproved pharmaceuticals will not support imposition of a monetary penalty.

Article 2, Paragraph 1, Items (ii) and (iii) of the PMDA states that "pharmaceuticals" are defined as objects that are intended to have medical effect regardless of whether they actually have that effect:

Article 2, Paragraph 1 (Definitions)
The term "pharmaceutical" as used in this Act refers to the following items:

- items listed in the Japanese Pharmacopoeia;
- items which are intended for use in the diagnosis, treatment or prevention of disease in humans or animals, and which are not medical appliances or instruments, etc; and
- items which are intended to affect the structure and functioning of a human or animal's body, and which are not medical appliances or instruments, etc (excluding quasi-pharmaceutical products, cosmetics, and regenerative medicine products).

Thus, health food products distributed with a statement indicating that they have medicinal effects also constitute "pharmaceuticals" under the PMDA, even though those products have not been approved pursuant to the PMDA. Therefore, those health food products constitute unapproved pharmaceuticals, advertising of which violates Article 68. The current amendment to the PMDA excludes violation of Article 68 as basis for a monetary penalty, although lawmakers discussed inclusion thereof.

However, if the advertised medicinal effects of health food products are false or exaggerated, the advertising would constitute a violation of Article 66 and may be the basis for a monetary penalty.

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