

**Official Notice
May 10 2018**

To: Pharmaceutical Research and Manufacturers of America
European Federation of Pharmaceutical Industries and Associations

Economic Affairs Division
Health Policy Bureau
Ministry of Health, Labour and Welfare

Q&A on the considerations under the Antimonopoly Act for the initiatives of trade associations concerning the 'Guidelines for compliance by distributors for the improvement of ethical drug distribution'

The attached Official Notice concerning the above matter has been issued to the relevant associations and therefore we also forward it to yours. We request that it is disseminated to the members etc. thereof.

We apologize for the delay with this communication.

We shall continue to forward notices on the improvement of ethical drug distribution to your associations and request your appropriate handling thereof.

Further, for your reference we attach the following data.

- 'Guidelines for compliance by distributors for the improvement of ethical drug distribution' (English versions of Notifications HPB No. 0123-9 and HIB No. 0123-3 dated January 23 2018)

To: (See 'List of Recipients')

Q&A on the considerations under the Antimonopoly Act for the initiatives of trade associations concerning the 'Guidelines for compliance by distributors for the improvement of ethical drug distribution'

With a view to improving the distribution of ethical drugs, the 'Guidelines for compliance by distributors for the improvement of ethical drug distribution' were released on January 23 2018 and applied from April 1 2018.

The attached Q&A on the key considerations under the Act on Prohibition of Private Monopolization and Maintenance of Fair Trade (Law No. 54, 1947; hereinafter 'Antimonopoly Act') concerning the initiatives of distribution-related trade associations based on the guidelines have recently been compiled and accordingly we request that they be disseminated to your members etc.

Further, potential issues concerning the Antimonopoly Act may arise in connection with actions not listed here, in which case this Act and related guidelines (*) should be taken note of.

* The Japan Fair Trade Commission website:
<http://www.jftc.go.jp/dk/guideline/index/html>

LIST OF RECIPIENTS

Japan Medical Association
Japan Dental Association
Japan Pharmaceutical Association
Japanese Society of Hospital Pharmacists
Nippon Pharmacy Association
Japanese Nursing Association
Japanese Midwives Association
Japan Association for Clinical Engineers
Association of Japanese Healthcare Corporations
All Japan Hospital Association
Japan Municipal Hospital Association
Japan Psychiatric Hospitals Association
Japan Hospital Association
Japan Association of Private Medical Schools
Japan Association of Private Dental Schools
Japan National Health Insurance Clinics and Hospitals Association
Japan Hospital Federation
Social Welfare Organization Saiseikai Imperial Gift Foundation
Federation of National Public Service Personnel Mutual Aid Associations
Hokkaido Shakai Jigyuu
National Mutual Insurance Federation of Agricultural Cooperatives
National Federation of Health Insurance Societies
Federation of Pharmaceutical Manufacturers' Associations of Japan
Japan Pharmaceutical Manufacturers Association
Federation of Japan Pharmaceutical Wholesalers Association
NJIHK
Japan Dental Trade Association

Q1. What type of initiatives by trade associations for the purpose of complying with the distribution improvement guidelines are prohibited under the Antimonopoly Act?

A1. Actions that, notwithstanding their inclusion in the distribution improvement guidelines, restrict the free and fair transactions of constituent traders (pricing, supply volumes etc.) as a result of decisions taken by the association.

Q2. Would the following consultations and debates in the course of trade association activities for the purpose of complying with the distribution improvement guidelines present issues under the Antimonopoly Act?

(1) Discussion or information exchanges in trade association meetings on the following agenda items

- Factoring of allowances into invoice prices
- Contractual clarification of allowances and rebates
- Conclusion of memorandum-based single-product, single-price agreements
- Price negotiations benchmarked on the distribution cost ratio etc. included in drug prices (3-year average of distribution costs or 2% adjustment margin)
- Delivery prices that eliminate negative primary margins
- Conclusion of agreements on returns based on model contracts, and other matters concerning prices or trading terms

(2) Decisions in trade association meetings to the effect that constituent traders shall in principle engage in transactions described in (1)

(3) Discussions or information exchanges in trade association meetings concerning the interpretation of the official administration of the distribution improvement guidelines

A2. Information exchanges in meetings on the guidelines or on the interpretation of their official administration to promote compliance with the guidelines are not per se precluded.

However, decisions in meetings on pricing and trading terms etc. made jointly between trade associations or traders, or the coercion of constituent traders into such decisions would present issues under the Antimonopoly Act.

In addition, even where no explicit decisions are made by trade associations, tacit approvals or common understandings on competition restriction over pricing and trading terms may be formed between constituent traders through personal

approaches outlined in meetings by an individual constituent trader. Any resulting substantive restrictions on market competition would present issues under the Antimonopoly Act.

Whether or not an action presents an Antimonopoly Act issue shall be assessed on a case-by-case basis depending on the specific individual circumstances.

Q3. Would discussions in trade association meetings on items in the distribution improvement guidelines with the presentation of specific criteria (*) be an action corresponding to unfair trading restrictions (in terms of cartels, bid-rigging (dango) etc.)?

*** For example, with reference to the consideration in downstream transactions of 'excessive discount negotiations in disregard of the value of a drug', requests in negotiations for the minimum distribution cost ratio etc. included in drug prices (3-year average of distribution costs or 2% adjustment margin)**

A3. Actions to restrict competition through liaison between traders or trade associations to agree jointly on matters such as product prices or sales/production volumes that should primarily be determined independently by each trader are prohibited as 'cartel' trading, irrespective of their format, whether a gentleman's or a verbal agreement etc.

Accordingly, decisions in meetings on prices and trading terms etc. made jointly between trade associations or traders, or the coercion of constituent traders into such decisions would present issues under the Antimonopoly Act.

With reference to the distribution cost ratio etc. referred to in the guidelines, this also applies to decisions on discount benchmarks etc. and coercion into decisions.

In addition, even where no explicit decisions are made by trade associations, tacit approvals or common understandings on competition restriction over prices and trading terms may be formed between constituent traders through personal approaches outlined in meetings by an individual constituent trader. Any resulting substantive restrictions on market competition would present issues under the Antimonopoly Act. (*)

* From fiscal 2008 the Japan Fair Trade Commission has been posting on its website cases where cease and desist orders have been filed against trade associations or traders for violations of the Antimonopoly Act. (<http://www.jftc.go.jp/dk/ichiran/index.html>)

Whether or not an action presents an Antimonopoly Act issue shall be assessed on a case-by-case basis depending on the specific individual circumstances.

Q4. Please give advice on the Antimonopoly Act compliance initiatives that trade associations should take.

A4. Mindset reform to highlight the importance of compliance by trade association representatives, the drafting of related manuals and training sessions can be cited as Antimonopoly Act compliance initiatives by trade associations.

An immediate initiative could be for all trade association meeting attendees to confirm mutually the following items.

- That the meeting to be held complies with the Antimonopoly Act and related laws
- That no decisions on prices or trading terms shall be made at the meeting to be held
- That no approaches by individual constituent traders are presented at the meeting on pricing and trading term matters etc.

Further initiatives could be to include lawyers or other independent specialists in meetings, or to ensure that minutes of meetings are retained.

Q5. Where a trade association prepares a 'PR medium on compliance with the distribution improvement guidelines' for its members, would specification therein of matters such as the following present issues?

- **Showcasing examples that do not correspond to single-product, single-price agreements**
- **Setting out the considerations for price negotiations**
- **Encouraging companies to try at their own discretion to recommend negotiating parties in agreements to enter into lengthier agreements.**

A5. As long as member companies carry out their business activities at their own discretion in accordance with the guidelines without hindering their fair and free competition, the specification of such details are not precluded.

However, even where no explicit decisions are made by trade associations, tacit approvals or common understandings on competition restriction over pricing and trading terms may be formed between members through the respective statements. Any resulting substantive restrictions on market competition would present issues under the Antimonopoly Act.

Whether or not an action presents an Antimonopoly Act issue shall be assessed on a case-by-case basis depending on the specific individual circumstances.