

Donation Guidelines

(Established on April 6, 2021)

1. Preamble

Under the national policy to promote collaboration and cooperation among industrial-academic-governmental circles as provided for in the Science and Technology Basic Plan, collaborative activities between the private sector and academic institutions have conventionally been promoted. The more these activities are promoted, the more opportunities there are for medical institutions and healthcare professionals to become deeply involved with specific companies or products, and concerns have been expressed that such collaborative activities may be affecting the judgment of these medical institutions and healthcare professionals to a certain degree.

Under such circumstances, several media outlets have reported cases where certain universities had a conflict of interest with specific companies that should have been disclosed but were not. This prompted the government to take initiative to establish the Advisor Group on Clinical Research, followed by the promulgation of the Clinical Trials Act.

In addition, both the healthcare industry and universities have started efforts to address such conflict of interest-related issues that can arise from donations. In 2011 and 2012, respectively, the Japan Pharmaceutical Manufacturers Association (JPMA) and the Japan Federation of Medical Devices Associations (JFMDA) developed information disclosure guidelines for the funding of medical institutions etc. as corporate activities and encouraged their respective member companies to make their donation-related information available to the public. Further, on the national university hospital side, the National University Hospital Council of Japan established the “Guidelines for Disclosure of Funding from Drug Makers and Other Companies” in 2014 with the objective of appropriately promoting collaborative activities among industrial-academic-governmental circles with social understanding and cooperation, on the conditions that national university hospitals, as public institutions, ensure transparent regarding funding from drug makers and other companies and that they possess high ethical standards. Many national universities are now promoting transparency by disclosing funding from companies and other bodies, but the current situation is that, with regard to donations, there is still no end to suspicions of conflicts of interest or collusive relationships between specific companies and medical institutions or healthcare professionals.

Considering such circumstances, AMDD decided to establish these guidelines so as to help its member companies to re-ascertain the purpose of promoting collaboration among industrial-academic-governmental circles and the meaning of donations made thereunder, and to ensure greater transparency when making donations to universities to contribute to the development of medicine and healthcare.

As stated above, in Japan, as part of the policy for industrial-academic-governmental collaboration, donations from the private sector are invited by universities, medical institutions, and other bodies, which play a leading role in many research organizations. A donation essentially represents the provision of money and articles for free, irrespective of any transaction. But in reality, the recipients of donations from medical device and IVD companies are also often the customers of those companies, so it cannot be denied that such companies may be unjustifiably providing money and articles under the name of donations. To prevent this, our guidelines will hopefully help member companies to establish a policy for proper donations.

2. Important points for using the Guidelines

The objective of establishing these guidelines is to serve as a useful reference for desirable donations that will help AMDD member companies to correctly understand the meaning of making donations, and to avoid donations that could be interpreted by third parties as being intended to induce transactions.

The important points for using these guidelines are as below.

1. These guidelines were established only as a reference for individual member companies as they prepare operating procedures for donations. The AMDD has no intention to obligate member companies to implement these guidelines. It is important for member companies to correctly understand the objectives and the significance of making donations and to proactively work against fraud.
2. These guidelines apply to donations or educational grants to universities known as “*shogaku kifukin*.” However, companies should establish separate operating procedures for properly making donations not covered by these guidelines.
3. We expect that the laws and standards related to these guidelines, including the FCC, will be revised as necessary going forward. These guidelines are consistent with laws and standards as of the time of preparation, but individual companies will need to revise their operating procedures to comply with any newly established laws or standards or any revisions to current laws or standards.

4. Donations are stipulated in detail by the FCC's Standards for Donations. Even if a company intends to make a donation in compliance with these guidelines, it still needs to ensure compliance with the FCC's Standards for Donations. If a company has any doubts about the FCC, we recommend consulting the Japan Fair Trade Council of the Medical Devices Industry.

3. Guidelines (Establishing an Internal Structure)

Internal Structure

- Companies must establish an appropriate internal structure to prevent donations intended to induce transactions and violations of the Fair Competition Code of the Medical Devices Industry in Japan and corruption-related laws and regulations (including criminal laws and FCPA).
- The appropriate internal structure should include application procedures (processes) for donations, necessary documents to be included when applying, and approval authority. These should be stipulated in internal rules and standard operating procedures (SOP), which must be created as part of the establishment of the appropriate internal structure.

(Commentary)

Donations that are intended to induce transactions are prohibited by the FCC and may constitute violations of the FCPA. For this reason, a company needs to (i) establish an internal structure and processes, before making a donation, to ensure that a financial contribution in the name of a donation is not aimed to induce transactions, (ii) prevent donations made for the purpose of inducement of transactions through such structure and processes and (iii) reduce the risk of third parties mistakenly suspecting the donation as such.

Documenting and stipulating such internal structure and processes for donations in internal rules and internal standard operating procedures (SOP) makes it easier to clarify the matters to be confirmed before and after making a donation and also to avoid confusion about application/approval procedures in relation to personnel changes or wasted effort during internal audits. Also, we strongly recommend that such documents be prepared in writing, as written internal rules and SOPs can likely serve as strong evidence to protect a company during regulatory inspection.

Budgetary Control

- Donations should preferably be made without breaking the annual donation budget that was prepared at the beginning of the fiscal year and approved. In addition, it is recommended that the donation budget be separate from departments comprising of those who are involved in sales activities and routinely interact with HCPs and be managed as part of company-wide expenses.

(Commentary)

To demonstrate that a financial contribution in the name of a donation is not intended to induce transactions, it is ideal to eliminate the involvement of those who are involved in sales activities and routinely interact with HCPs in the donation as much as possible. For example, one good budgetary management method to ensure that the donation amount cannot be adjusted depending on the university's transaction amount is to freeze the total donation budget at the beginning of the fiscal year to put it outside the control of departments comprising of those who are involved in sales activities and routinely interact with HCPs.

Requests for Donations

- It is preferable for companies to establish a department (or deploy personnel) to act as a contact for university requests for donations.
- Applications for internal approval of donations should preferably be planned by a department other than departments comprising of those who are involved in sales activities and routinely interact with HCPs.
- The following materials (or similar) should generally be included with an internal application for donation.
 - a) Documents showing reasons why the donation is needed (e.g. prospectus),
 - b) Rules for handling donations,
 - c) A research plan for the research to which the donation is directed and the revenue and expenditure plan thereof,
 - d) Documents showing the activities of the candidate donation recipient for the previous fiscal year, such as research reports from their institution,
 - e) Revenue and expenditure statements for the previous fiscal year, and
 - f) Other notable information about the candidate donation recipient.

(Commentary)

Since many universities are taking proactive measures to invite scholarship donations or other external funds, we can easily assume that the university staff will speak with a sales representative, etc. who acts as a contact person for the business entity about requests from universities for economic support for

medical/educational activities. It is therefore desirable to confine the involvement of departments comprising of those who are involved in sales activities and routinely interact with HCPs only to introducing the department in charge of donations to universities when receiving such a request for donations by a university, so that the donation is not misinterpreted by external third parties as being intended to induce transactions despite having been made purely for public interest purposes as part of internally planned social activities.

A subsequent internal application for deliberation about the donation should also preferably be planned by the department (personnel) in charge of donations, or any department other than the departments comprising of those who are involved in sales activities and routinely interact with HCPs, using pre-determined application forms. This application should not include opinions from the sales and other commercial department.

In addition, to support the internal application and ensure that the donation will be made for public interest purposes, for companies with an SOP that requires document routing as a means of approval, for example, it is wise for the university's prospectus for the donation and rules for handling donations and other such information to be routed to approvers along with the donation application.

The method of receiving university requests for donations should be established according to the circumstances of each business entity. Methods adopted by some companies are given below for reference.

- Accepting direct applications from universities via the internet
- Application via e-mail to an address specifically for donation-related correspondence
- Establishing a contact department dedicated to donation management that is independent of departments comprising of those who are involved in sales activities and routinely interact with HCPs and that handles everything from communication with universities to donation payment, including management of internal applications.

When a company organizes a donation program and solicits applications, it is also desirable to solicit applications publicly or otherwise make it widely known.

Internal Approval

- Those who are involved in sales activities and routinely interact with HCPs must be kept away from internal approval for donations.
- Companies should preferably establish a department or deploy personnel capable of providing objective advice about whether a donation is appropriate from various viewpoints such as medicine, education, and science, and should involve such department or personnel in internal approval for donations.

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| <ul style="list-style-type: none">● Companies should preferably define clear criteria for determining the appropriateness of the amount to be paid before receiving any application for a donation. |
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(Commentary)

To avoid having donations determined in the aim of inducing transactions and to avoid the risk of third-party suspicions of such donations, it is important to keep those who are involved in sales activities and routinely interact with HCPs away from donation approval.

In addition, since donations are intended to foster university education and research, one of the donation approvers should preferably be any department or expert (e.g. medical affairs, clinical affairs, medical specialists) with sufficient knowledge to determine the appropriateness of the planned activities of the candidate donation recipient. If such a department or expert cannot be one of the approvers, it is preferable to involve them in the approval process by having them give opinions to the approvers.

As with methods of receiving university requests for donations, it is a wise choice to establish appropriate internal approval methods for donations according to the circumstances of individual companies. To this end, the following examples from some companies should be taken into consideration.

- Establishing an expert committee composed of multiple members who are not from the departments comprising of those who are involved in sales activities and routinely interact with HCPs and having such committee approve donations.
- Inviting external experts from the medical, educational, and scientific fields as independent third parties to deliberations in the expert committee described above.
- Delegating internal approval authority to different approvers depending on the donation amount.
- After internal review of applications, leaving the final review and approval to the overseas parent company.

Before approval, it is also important to define clear criteria for determining whether a donation may be paid or whether a donation amount is appropriate. For example, to demonstrate that decision on and approval of the donation amount are independent of the transaction amount, some companies have set a ceiling on the amount of a donation to a single university or its proportion to the total amount of donations, or have a rule that if donations are paid to multiple universities, the same amount should be given to every university wherever possible.

Payment

- Donations should be paid in accordance with the donation-handling rules of the approved donation recipient.
- Before paying a donation, it is preferable to conclude a written contract of some kind with the donation recipient.

(Commentary)

If an internal application for a donation is approved and donation-handling rules have been obtained from the candidate donation recipient, it is important to pay the donation in accordance with such rules. If no donation-handling rules are available, obtaining alternative documents from the university that show the clerical work related to receiving donations would be a wise choice. Payment to any arbitrary bank account not listed in the donation-handling rules or documents about the clerical work related to receiving donations may be interpreted as not being a donation but rather intended to induce transactions fraudulently. From that perspective, check carefully whether the bank account is appropriate before starting payment procedures.

Before paying a donation, the business entity should also preferably conclude a donation contract, letter of confirmation, letter of undertaking, or whatever other formality in writing or other equivalent means in order to have the university promise to use the donation exclusively for the purpose approved by the business entity.

Record-keeping

- A document should be retained that demonstrates that there were no personnel who are involved in sales activities and routinely interact with HCPs among the decision-makers for the internal approval of the donation.
- After making a donation, companies should receive a brief report about what the money was used for and a final result report from the donation recipient.
- After making a donation, the business entity must appropriately disclose the donation amount in accordance with the transparency guidelines issued by the JFMDA.

(Commentary)

It is important for companies to retain written records of internal approval for the donation so as to ensure explanatory ability and transparency at a later date. For example, such records may include the minutes of a committee meeting that names the participants, if the business entity has established an approval committee.

Companies should preferably have processes for, after making a donation, receiving a brief report about what the money was used for and disclosing the donation amount. These are required by the FCC and

by the transparency guidelines issued by the JFMDA. Companies should take actions in accordance with such rules at minimum.

If receiving a brief report about an endowed lecture course provided over multiple fiscal years, it would be wise for the company to request the submission of interim revenue and expenditure statements or research reports around the same time as the donation payment.

Other

- The relationship to the Clinical Trials Act should also be taken into consideration.
- Companies must not have their employees make donations on behalf of or for the company.
- It is desirable for companies to repeatedly provide training to their employees so that they have a thorough understanding of the purpose of donations.

(Commentary)

Check whether the research to which the donation is directed falls under the category of specified clinical trials as defined in the Clinical Trials Act. If it does, take appropriate measures in compliance with the Clinical Trials Act.

Another point to consider is that, if a donation was rejected but the company still wishes to pay it, this does not justify having or allowing an individual employee to make a donation. Needless to say, companies must not give permission to have an individual employee make a donation in the name of or on behalf of the company.

Even if a donation is made in accordance with the internal SOP, it may possibly be misunderstood as inducement of transactions or otherwise being for a purpose other than its original purpose, due to circumstances outside of the SOP that would invite suspicion, such as improper communications with HCPs. Companies should therefore continuously make efforts for their employees to have a thorough understanding of the purpose of donations through internal training, etc.

Issued by AMDD Legal & Compliance Committee
(AMDD: American Medical Devices and Diagnostics Manufacturers' Association, general
incorporated association)