Transparency Guidelines for Chugai Activities Involving Medical Institutions and Healthcare Providers

Chugai is committed to improving the transparency and trustworthiness of its corporate interactions with medical institutions and healthcare providers through cooperation with these groups. We ask medical institutions and healthcare providers to work with us to achieve the objective of these guidelines.

Chugai Pharmaceutical Co., Ltd.

1. Background

a. Ensuring Ethical Standards

The World Medical Association (WMA) has provided guidelines for appropriate interactions between physicians and commercial enterprises in its "WMA Statement concerning the Relationship between Physicians and Commercial Enterprises." Those guidelines state that "The combination of financial resources and product knowledge contributed by industry and the medical knowledge possessed by physicians enables the development of new diagnostic procedures, drugs, therapies, and treatments and can lead to great advances in medicine. However, conflicts of interest between commercial enterprises and physicians occur that can affect the care of patients and the reputation of the medical profession....Rather than forbidding any relationships between physicians and industry, it is preferable to establish guidelines for such relationships. These guidelines must incorporate the key principles of disclosure, avoidance of obvious conflicts of interest and the physician's clinical autonomy to act in the best interests of patients." (excerpt from Japan Medical Association website).

b. Ensuring Trustworthiness

In its final recommendations in April 2010, the Committee for Investigation of Drug-Induced Hepatitis Incidents and Review of Pharmaceutical Administration to Prevent Recurrence stated that "It has also been pointed out that drug-induced suffering occurs against a backdrop of interdependence (e.g., conflicts of interest) between commercial enterprises and the state, universities, medical institutions, academic societies, and healthcare providers, and it is essential that there be a change in the mindsets of corporations and other involved parties." Interaction between pharmaceutical companies and medical institutions and healthcare providers is essential for delivering the most appropriate drugs to patients, but it is important that this relationship be trusted as an ethical and honest one in which patient health is given first priority.

c. Ensuring Transparency

While the final recommendations referred to in (b) also called for appropriate management of conflicts of interest and action to increase transparency as is being implemented overseas, and initiatives are also being taken to manage conflicts of interest in Japan by bodies such as the Ministry of Education, Culture, Sports, Science and Technology, the Ministry of Health, Labour and Welfare, and the Japanese Association of Medical Sciences. Clarifying the involvement of enterprises in line with these guidelines concerning various industry-academia collaborations involving pharmaceutical companies and healthcare providers is seen as a step towards ensuring trustworthiness in industry-academia collaborations.

d. Towards the Sound Development of Industry-Academia Collaborations

Industry-academia collaborations are a vital part of medical and pharmaceutical science research, and disseminating information on their practical application and proper use. Unfortunately, the more extensive such collaborative efforts become, the more likely it is that medical institutions and healthcare providers become deeply involved with specific companies and products, and the concern that this influences the decisions of said medical institutions and healthcare providers cannot be denied. The present guidelines were developed in 2011 because the Japanese pharmaceutical industry has an even greater responsibility than other industries to be transparent in its activities, given that it is a life-related industry that operates under a universal public healthcare system and is closely involved in the lives and health of patients and the public.

e. Relation to the Clinical Trials Act

The Clinical Trials Act was enacted on April 1, 2018, obligating the public disclosure of funding information pertaining to specified clinical trials subject to the Clinical Trials Act. As there are slight discrepancies in the obligatory public disclosure matters stipulated by the Clinical Trials Act and information previously released in accordance to these guidelines, these guidelines will be partially revised to resolve these discrepancies between the Clinical Trials Act and these guidelines. This, together with additional efforts to improve transparency, will be implemented in an aim to prove the trustworthiness of our clinical research activities to the people of Japan.

2. Purpose

Chugai aims to demonstrate to the wider community that the pharmaceutical industry is contributing to the advancement of the medical and pharmaceutical sciences and other life sciences and that Chugai's corporate activities are based on high ethical standards, by ensuring the transparency of its interactions with medical institutions and healthcare providers.

3. Funding Recipients Subject to Disclosure

a. Medical Institutions

Hospitals, clinics, long-term care health facilities, pharmacies, and other institutions that provide medical care

b. Research Institutes

i. Research departments associated with medical institutions (such as Research departments associated with laboratories in the National Cancer Center and laboratories in the National Cerebral and Cardiovascular Center).

ii. Medical and pharmaceutical science departments in universities and Academic Research Organizations (ARO)

iii. University research departments in the life sciences, such as the physical sciences and engineering

iv. Other life science research departments

c. Medical Bodies

Medical and pharmaceutical bodies such as doctors' and pharmacists' associations and medical and pharmaceutical science associations

d. Foundations

i. Medical and pharmaceutical foundations (e.g., incorporated bodies, foundations, corporate enterprises, NPOs, associations).

ii. Bodies that manage research funding for specific clinical research activities (including CROs)

e. Healthcare Providers

Healthcare practitioners (physicians; dentists; pharmacists; nurses, including public health nurses; and other healthcare professionals), medical service personnel (medical institution board members and employees and those involved in selecting or purchasing prescription drugs at the medical institution, other than healthcare practitioners), and medical and pharmaceutical researchers or life science researchers in fields such as the physical sciences and engineering

Medical institutions Hospitals, clinics, long-term care health facilities, pharmacies, and other institutions that provide medical care

4. Funding Subject to Disclosure

a. Funds will be disclosed regardless of the value.

b. Funding via third parties such as subcontractors or foundations will also be disclosed.

c. Funds include drugs and devices given in kind. This does not include drug samples for clinical trialing, drug product samples

for checking dosage form and appearance, or investigational medicinal products.

d. Funds for supporting membership fees and advertising fees not associated with the holding of a meeting such as an academic conference are not included.

e. Funding of events co-hosted by recipients who are subject to disclosure in these guidelines, and by patient groups or patient support groups, will be disclosed in accordance with these guidelines rather than Transparency Guidelines for the Relation between Corporate Activities and Patient Groups.

5. Form of Disclosure

a. Method of Disclosure

Information will be disclosed via the Company's website.

b. Timing of Disclosure

Information will be disclosed within one year upon the completion of every Chugai business year from FY2019 (January to December 2019) onwards.

c. Subject to disclosure

A. Research and Development Expenses

The total annual expenditure for each item, including expenses for research and development of prescription drugs and for post-marketing drug development will be disclosed as follows.

Category	Details	Form of disclosure
Expenses for specified clinical trials	Funds provided to medical institutions to perform specified clinical trials based on the Clinical Trials Act	ID recorded to the jRCT (Japan Registry of Clinical Trials) (hereafter, research ID), name of recipient institution, general manager name, name of the medical institution performing the research activity, names of affiliates, name of doctor in charge of/responsible for research, number of contracts, amount paid
Research expenses based on ethical guidelines	Funds provided to medical institutions to perform research based on the "Ethical Guidelines for Medical and Biological Research Involving Human Subjects (Medical and Biological Guidelines)"	Name of the recipient institution, number of contracts with payments that year, amount paid
Non-clinical research expenses	Funds provided to medical institutions for research activities other than "clinical research from phase I" (e.g. basic research, pharmaceutical preparation research)	List of names of recipient institutions
Clinical trial expenses Post-marketing clinical study expenses	Expenses for clinical trials, post-marketing clinical trials, adverse drug reaction and infection case reporting and post-	Name of the recipient institution, number of contracts with payments that year, amount paid

Adverse drug reaction and infection case reporting expenses	marketing surveillance implemented based on the pharmaceutical regulations such as GCP/GVP/GPSP ordinance.	
Post-marketing surveillance expenses trials	Clinical trial expenses will include funds provided for investigator-initiated clinical	
Other costs	Funds provided to those other than recipients who are subject to disclosure	

a. Research funding provided to SMOs/CROs will be treated in the following manner.

i. When outsourcing non-specified clinical trial research activities to CRO.

Release information on research funding provided to each medical institution via the CRO under the name of each medical institution.

In this instance, the name of the CRO does not need to be disclosed.

ii. If the CRO is involved in management of the funding for specified clinical trials

Information pertaining to the "research funding" provided to the CRO and all research funding indirectly provided to each medical institution is subject to public disclosure.

In this instance, the name of the CRO responsible for managing funding is subject to public disclosure.

iii. If research funding is directly provided, in part, to the CRO entrusted with operations by a medical institution Funding provided to CRO will also be listed under the name of the medical institution as research funds provided to said medical institution.

b. Any equipment loaned out to perform such research activities is not subject to public disclosure.

c. Expenses categorized as "Lecturer honoraria," "Manuscript writing and editorial supervision fees," or "Other outsourcing expenses" will be disclosed under Section C. "Manuscript Writing Fees, etc." However, case reporting expenses will be disclosed under Section A. "Research and Development Expenses" rather than Section C. "Manuscript Writing Fees, etc." even if paid to an individual.

d. When disclosing information on specified clinical trial expenses, if a research ID has not been provided at the time such information is first disclosed, leave this field blank, and promptly disclose said research ID at a later time after it is provided. In this instance, form contracts and take other such measures to ensure that the recipient institution provides the said research ID in a prompt manner.

e. When disclosing information on specified clinical trial expenses, if research funding is provided to a medical institution performing the research activity via a body overseeing said research, form contracts with said body and take other measures to ensure that information required for disclosure can be obtained so as to meet all legal requirements. Distinguish funding provided to the medical institution performing the research activity via a managing body in parentheses, or by using notation to similar effect.

f. The name of the recipient institution will generally be the name of the contract partner.

g. Patient pay and clinical trial participation expenses paid to subjects of clinical trials via the medical institution will be disclosed as funding provided to the medical institution.

h. With the exception of specified clinical trial expenses, any expenses paid as compensation to subjects of clinical trials for any health damages caused will not be disclosed, even if paid via the medical institution.

i. All expenses paid to IRBs (including certified review boards) may be disclosed under the name of the medical institution to which the doctor leading the research belongs.

j. Expenses incurred for statistical analysis as part of "specified clinical trial expenses," "research expenses based on ethical guidelines" and "non-clinical research expenses" will be disclosed as funding provided to the medical institution. All incurred for statistical analysis may be disclosed under the name of the institution to which the doctor leading

the research belongs.

Expenses incurred for statistical analysis other than the above will be disclosed as "Other expenses" in Section A.

k. Expenses associated with the holding of meetings not paid to the medical institution. (e.g. venue fees, catering expenses, travel costs) will be disclosed as "Other expenses" in Section A.

l. Testing costs not paid to the medical institution will be disclosed as "Other expenses" in Section A. However, funding paid directly to the testing company for specified clinical trials based on a three-way contract formed with the medical institution/testing company will be disclosed as funding provided to the medical institution.

m. Information on prescription drugs or bulk drug substance provided for research activities (excluding studies and trials performed based on GCP/GVP/GPSP ordinances) will be disclosed as the "name and quantity of the material provided" under the relevant field in Section A. "Research and Development Expenses."

n. With the exception of specified clinical trial expenses, detailed information concerning research activities contracted before the 2015 fiscal year will not be disclosed.

o. Of research based on "Medical and Biological Guidelines," funds that are applicable to research activities other than "Phase I and subsequent clinical studies" (e.g., basic research, pharmaceutical preparation research) will be disclosed as the category, "Non-clinical research expenses."

B. Academic Research Support Expenses

Funding to promote and support academic research will be disclosed together with the total annual expenditure for each category as follows.

Category	Details	Form of disclosure (example)
Scholarship donations	Donations to university schools of medicine and medical institutions with associated research institutes, and donations to fund research for which applications are made	xx Department, xx University: Number of donations, xx Yen xx Department, xx Medical Center: Number of donations, xx Yen
General donations	Donations that do not come under "Scholarship donations" or "Donations to academic societies"; provision of prescription drugs free of charge; in-kind donations; provision of bulk drug substance; and donations to foundations	xx University (xx Foundation): Number of donations, xx Yen xx Department, xx University: xx g of xx bulk drug substance
Donations to academic societies	Donations to academic societies for expenses for meetings and other society activities	xx (th) xx Society Meeting: xx Yen xx (th) Public Health Course, xx Executive Committee: xx Yen
Academic society co-hosting expenses, etc.	Expenses paid to a co-host such as for funds other than donations provided when a holding a meeting such as an academic conference or scientific meeting and for co-hosted lecture meetings, etc.	xx Seminar, xx (th) xx Society Meeting: xx Yen xx Advertising fees for xx (th) xx Society Meeting: xx Yen xx Exhibition fee for xx (th) xx Society Meeting: xx Yen xx Sponsorship for xx (th) xx Society Meeting: xx Yen xx (th) xx Society Meeting: xx Yen xx Medical Association Lecture Meeting: xx Yen, etc. (Display such that co-hosts can be identified)

a. For endowed chairs, the title of the chair and the number of chairs and total amount of funds for that year will be disclosed under the category "Scholarship donations."

b. Donations to foundations

i. Donations to foundations will be disclosed individually as general donations.

ii. If it is obvious that donations are provided to a medical institution or healthcare provider via a foundation, the donations will be disclosed individually, including the names and other relevant details of the foundation and the medical institution or healthcare provider. If the foundation discloses the funding source and the recipient medical institution

or healthcare provider, only donations to the foundation will be disclosed.

iii. For donations to academic societies via foundations, the name and other details of the academic society will be disclosed but the name of the foundation does not need to be disclosed.

c. Provision of drugs

The provision of drugs free of charge as a medical support measures (excluding donated provisions in times of emergency) will be disclosed as "General donations." If there are multiple recipient institutions, the name of the medical institution to which the head requester belongs will be disclosed as the representative institution. Further, drugs, etc. provided for research activities will be disclosed under the relevant field in Section A. "Research and Development Expenses." (See item (13) in the description of A. "Research and Development Expenses").

d. Donations to academic societies

i. Donations to medical bodies will all be disclosed as "Donations to academic societies."

ii. Donations for international academic conferences will be disclosed if a Japanese recipient who is subject to disclosure hosts the conference or plays an equivalent role (e.g., seeking donations), regardless of the location (country) in which the conference is held.

e. Academic society co-hosting expenses, etc.

i. All meetings co-hosted with medical bodies will be subject to disclosure as academic society co-hosting expenses and will be disclosed such that the co-host can be identified. Seminar co-hosting expenses, advertising fees, exhibition fees, and sponsorship fees will be disclosed separately.

ii. Academic society co-hosting expenses, etc. include expenses such as "seminar co-hosting expenses," "expenses for advertisements posted on academic society websites and abstract proceedings, etc.," "fees for exhibits in exhibition booths," and "sponsorship fees with multiple privileges."

iii. For academic society co-hosting expenses, funds paid to the co-host will be subject to disclosure.

iv. Honoraria to presenters will be disclosed under "Lecturer honoraria" in Section C. "Manuscript Writing Fees, etc."

v. Expenses other than funds paid by Chugai to co-hosting bodies (e.g., cost of venue use, meal charges for attendees, travel and accommodation costs for presenters) will be disclosed as " Expenses for lecture meetings and other meetings" in Section D. "Expenses Related to Provision of Information."

C. Manuscript Writing Fees, etc.

Expenses paid in return for lectures, manuscript writing and editorial supervision, or other outsourced work that is for the provision of medical or pharmaceutical scientific information, including information on Chugai drugs, or that is related to research and development will be disclosed as follows.

Category	Details	Form of disclosure (example)
Lecturer honoraria	Lecturers, chairpersons, panelists, etc.	Professor xx, xx Department, xx University: xx Number of payments, xx Yen
Manuscript writing and editorial supervision fees		xx Manager, xx Department, xx Hospital: xx Number of payments, xx Yen
Other outsourcing expenses	Payments in return for consulting and other outsourced work that does not come under lectures or manuscript writing and editorial supervision	Professor xx, xx Department, xx University: xx Number of payments, xx Yen

a. Payment recipients and information disclosed

i. The expenses in Section C. "Manuscript Writing Fees, etc." are generally paid to individual contractors, and the name of the department and institution with which the contractor is affiliated and the name and title of the individual contractor will be disclosed.

ii. If the payments in Section C. "Manuscript Writing Fees, etc." are made to the medical institution with which the

individual contractor is affiliated, the name of the medical institution with which the individual contractor is affiliated and the number of payments and the amounts paid will be disclosed, but the name and other details of the individual contractor will not be disclosed.

iii. If manuscript writing fees, etc. are paid to an incorporated body other than the medical institution at which the individual contractor is working, the name and other details of the incorporated body, the individual contractor, and the medical institution with which the individual contractor is affiliated, the number of payments, and the amount paid will be disclosed.

iv. Payments in Section C. "Manuscript Writing Fees, etc." in projects carried out through a vendor such as an advertising agency or planning company will generally be made directly by Chugai rather than by the vendor.

v. If the costs in Section C. "Manuscript Writing Fees, etc." are shared by multiple companies in the same industry, Chugai will obtain consent for disclosure from the relevant healthcare provider on behalf of the companies, and payments made directly by Chugai will be subject to disclosure by Chugai. Payments made directly by other companies in the same industry will not be included in payments subject to disclosure by Chugai.

vi. The amount including consumption tax, withholding tax on income, and special reconstruction income tax (in the case of payment to an individual contractor) will be disclosed.

vii. Necessary expenses such as accommodation and travel expenses are not included in Section C. "Manuscript Writing Fees, etc."

viii. "Other outsourcing expenses" include all honoraria paid to Japanese healthcare providers for outsourced work other than "Lecture honoraria" and "Manuscript writing and editorial supervision fees" (e.g., consultancy fees for academic advice; honoraria for discussion meetings, coordinator meetings, in-house training workshops, study meeting lecturers, and facility tour meetings).

b. Payments to board members, advisers, and occupational health physicians

Payments to those who qualify as recipients who are subject to disclosure will not be subject to disclosure if the recipient is a Chugai board member, adviser (former board member or status equivalent to former board member), or occupational health physician.

c. Patent royalties will not be subject to disclosure.

D. Expenses Related to Provision of Information

Necessary expenses for providing medical or pharmaceutical scientific information, including information on Chugai drugs, will be disclosed as follows.

Category	Details	Form of disclosure
Expenses for lecture meetings and other meetings	Travel and accommodation expenses, venue fees, and information exchange meeting expenses	Annual number of payments and total amount paid
Briefing expenses	Expenses for light refreshments, lunches, etc. during medical office briefings	Annual number of payments and total amount paid
Expenses for providing medical and pharmaceutical literature and other goods	Medical and pharmaceutical books, promotional complementary goods, required and useful goods, etc.	Total annual amount

E. Other Expenses

Expenses for hospitality as a social courtesy will be disclosed as follows.

Category	Details	Method of Disclosure
Hospitality expenses	Provision of food and beverages, etc.	Total annual amount

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