Transparency Guidelines for Relationships with Medical Institutions

01/January/2022
Nxera Pharma Japan Co., Ltd.

1. Purpose
   Nxera Pharma Japan will contribute to the development of life sciences, including medicine and pharmacy by ensuring transparency in its relationships with medical professionals and institutions.
   These guidelines are based on the "Regarding the Transparency Guideline for the Relation between Corporate Activities and Medical Institutions" issued by the Japan Pharmaceutical Manufacturers Association (JPMA) and are designed to ensure that corporate activities are conducted in a highly ethical manner.

2. Disclosure method
   The payments, etc. shall be disclosed through Nxera Pharma Japan website.

3. Timing of disclosure
   Information for each fiscal year will be made public at an appropriate time after the financial results for that fiscal year are finalized. The period will be six years, including the fiscal year in question.

4. Targets of disclosure and its contents
   The following items will be disclosed: "A. Research and development expenses, etc." "B. Academic research support expenses" "C. Manuscript/writing fees, etc." "D. Information provision-related expenses" "E. Other expenses" and their contents will be disclosed according to each item below.

A. Research and development expenses, etc.
   Research and development expenses, etc. include expenses required for research/surveillance, etc. conducted under public regulations and various policies such as the Clinical Trials Act and GCP/GVP/GPSP ordinances under the Pharmaceutical and Medical Device Act.
   Funds, etc. provided shall be disclosed as follows together with the annual total amount of each item.

➢ Specified clinical trial expenses (Note 1)	Name, etc. of the relevant institution, etc. (Note 2): Number of cases, XX yen
➢ Research expenses based on ethical guidelines (Note 3)	Name of the relevant institution, etc. (Note 4): Number of cases, XX yen
➢ Research expenses other than clinical trials (Note 5)	Annual number of cases/total amount, name of the relevant institution, etc.
➢ Clinical trial expenses	Name of the relevant institution, etc. (Note 4): Number of cases, XX yen
➢ Post-marketing clinical study expenses	Name of the relevant institution, etc. (Note 4): Number of cases, XX yen

➢ Adverse drug reaction/infection case reporting expenses	Name of the relevant institution, etc. (Note 4): Number of cases, XX yen
➢ Post-marketing surveillance Expenses	Name of the relevant institution, etc. (Note 4): Number of cases, XX yen
➢ Other expenses	Annual total amount

(Note 1) "Specified clinical trial expenses" refer to expenses paid pursuant to a contract for a specified clinical trial as defined in the Clinical Trials Act.

(Note 2) "Clinical trial identification number", "institution, etc. to which funds are provided", "name of medical institution conducting the research" and "name of principal investigator", etc. shall be disclosed.

(Note 3) "Ethical guidelines" as used for the "research expenses based on ethical guidelines" shall mean the "Ethical Guidelines for Medical and Biological Research Involving Human Subjects" (life/medical and health guidelines).

(Note4)For "name of the relevant institution, etc.", "name of the institution", "name of in-house organization" and "department/title/name of the individual" shall be disclosed based on the contents of the contract.

(Note 5) "Research expenses other than clinical trials" refer to expenses required for research other than a specified clinical trial, research based on ethical guidelines, clinical trials, or post-marketing surveillance, etc., such as the so-called "basic research" and "pharmaceutical research."

B. Academic research support expenses

Scholarship donations and general donations made for the purpose of promoting academic research and subsidizing research, etc., as well as donations to academic societies, etc. to support the costs of holding meetings of academic societies, etc. and expenses for co-sponsoring conferences of academic societies, etc.

Funds, etc. provided shall be disclosed as follows together with the annual total amount of each item.

➢ Scholarship donation	XX Department of XX University: Number of donations, XX yen
➢ General donation	XX University (XX Foundation): Number of donations, XX yen
➢ Donation to academic society, etc.	XXth XX Academic Society Meeting (XX Regional Meeting, XX Study Group Meeting): XX yen
➢ Expenses of co-sponsored conference, etc.	XXth XX Academic Society Meeting (XX Regional Meeting, XX Study Group Meeting): XX yen

(*This paragraph includes information obligated to be disclosed under the Clinical Trials Act.)

C. Manuscript/writing fees, etc.

Fees, etc. for provision of scientific information, etc. on the company's pharmaceutical products, medicine, and pharmacy or fees, etc. paid as consideration for lectures and writing or supervision of the manuscript that are related to research and development, or commissioning of services including consulting contracts, etc. Funds, etc. provided shall be disclosed as follows together with the annual total amount of each item.

➢ Lecture fees	Professor (Director) XX, XX Department of XX University (XX Hospital): Number of services, XX yen

➢ Manuscript writing fee/supervision Fees	Professor (Director) XX, XX Department of XX University (XX Hospital): Number of services, XX yen
➢ Consulting, etc. commissioning fees	Professor (Director) XX, XX Department of XX University (XX Hospital): Number of services, XX yen

(*This paragraph includes information obligated to be disclosed under the Clinical Trials Act.)

D. Information provision-related expenses
Expenses of lecture meetings and explanation meetings, etc. for providing information, etc. related to the company's pharmaceutical products, medicine and pharmacy to medical professionals.

➢ Expenses for meetings including lectures, etc.	Annual number of meetings and total amount
➢ Explanation meeting expenses	Annual number of meetings and total amount
➢ Medical/pharmaceutical literature, etc. supply expenses	Annual total amount

E. Other expenses
Expenses for hospitality, etc. as social courtesy

➢ Expenses for hospitality, etc.	Annual total amount

5. Adaptation started
These guidelines shall start to payments for new fiscal years beginning on or after January 1, 2022.

6. Supplementary provisions
Revised effective April 1, 2024 due to company name change.

Prepared in April 2024