Transparency Guidelines for Collaborative Relationships between Astellas Pharma Inc. and Medical Institutions

1. Objective of Disclosure

The Astellas Group (including Astellas Pharma Inc. and its domestic group companies, hereafter referred to as “Astellas”) collaborates with research organizations of universities and medical institutions to conduct basic medical and pharmaceutical research, clinical development of new pharmaceuticals, post manufacture and marketing information collection and safety assurance measures, among other various activities. At the same time, Astellas contributes to improvements in medical healthcare of patients through the provision of pharmaceutical products and vaccines. Therefore, collaboration between Astellas and research organizations of universities and medical institutions is essential in the implementation of these activities.

Academic-industrial collaboration activities between Astellas and academic research institutions include joint research, commissioned research, and support activities of academic research through donations and other means. The results of research derived from these types of collaborative efforts between academia and industry are effective in contributing to society by helping to raise the level of Japan’s medical services, and such collaboration are encouraged within the Japanese Government’s Basic Program for Science and Technology.

Moreover, pharmaceutical companies are obligated to collect, analyze, and assess data regarding the efficacy and safety of marketed medicines in collaboration with medical institutions and healthcare professionals, and to provide their findings and other information to healthcare professionals. Therefore, Astellas cooperates with specialist physicians to disseminate information on the proper use of medicines, share information designed to achieve higher levels of safety and efficacy of medicines, and exchange information on the latest findings for various medicines to as many healthcare professionals as possible through academic lectures, research conferences, and other methods.

These types of academic-industrial collaborations which are essential for medical and pharmaceutical research, commercialization of products, and diffusion of the proper usages of medicines are conducted through contracts formed with medical institutions and healthcare professionals. Because these activities often entail payment of fees in return for their contributions, Astellas maintains full compliance of laws and regulations including the Pharmaceutical Affairs Law, and implements measures to raise the transparency level of its business activities by complying with self-imposed regulations of the industry (1) and its own Code of Conduct. However, as our collaboration with medical institutions and healthcare professionals increases, it may appear that they are so closely associated with Astellas or its
medicines that concern may be raised that the objective judgment of these medical institutions and healthcare professionals could be influenced.

As stated above, while maintaining a high level of ethics in its business activities and seeking to gain the understanding of a wide range of the parties concerned, with the goal of contributing to the development of life sciences including medicine and pharmaceuticals, in compliance with the guidelines of the Japan Pharmaceutical Manufacturers Association (JPMA)(2), Astellas will disclose information about its collaboration with healthcare professionals as listed below.

1. *1 JPMA Corporate Activity Charter, JPMA Compliance Program Guideline, JPMA Promotion Code for Prescription Drugs, Fair Competition Code in Ethical Pharmaceutical Drugs Marketing Industry etc
2. *2 JPMA “Transparency Guidelines for the Relation between Corporate Activities and Medical Institutions”

Page Top

2. Disclosure Method

Disclosure will be made on Astellas’ website or through other means.

3. Disclosure Timing

Information for the results of fiscal year 2012 will be disclosed at an appropriate time after the closing of the financial accounts for fiscal year 2012. In each year thereafter, information will be disclosed at an appropriate time after the closing of the financial accounts for each fiscal year.

4. Disclosure Details

Details about payments made to healthcare professionals in exchange for their collaboration will be disclosed in accordance with the categories listed below.

A. Research and Development Expenses

1. Joint research expenses
2. Commissioned research expenses
3. Clinical trial expenses
4. Post-marketing clinical trial expenses
5. Adverse events, infection case reporting expenses
6. Post marketing surveillance expenses

B. Academic Research Support Expenses

1. Scholarship donations
2. General donations
3. Academic conference donations
4. Cosponsored academic conference hosting expenses

C. Lecture, Other Fees

1. Lecture fees
2. Manuscript, writing fees
3. Consulting, consignment fees

D. Expenses for Information Provision

1. Lecture expenses
2. Explanatory meeting expenses
3. Medical, pharmaceutical literature provision expenses

E. Other Expenses

1. Entertainment expenses

5. Others

Important revisions of this policy will be determined by our managing director.