ETHICAL
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Fostering ethical exchange of information to improve patient care

Frequently Asked Questions About the Sunshine Act

Takeda Oncology is the brand name for the Global Oncology Business Unit of Takeda Pharmaceutical Company Limited, headquartered in Cambridge, Massachusetts, USA on the former Millennium Pharmaceuticals, Inc. site. The Takeda Oncology brand unifies our operations across our global footprint of the Oncology Business Unit, Oncology Therapeutic Area Unit (R&D) and Oncology Drug Discovery Unit. All Takeda Oncology payments that are provided by this legal entity will be reported under **Millennium Pharmaceuticals, Inc.** for Sunshine Act/Open Payments reporting.

We remain dedicated to patients and to conducting our business in the most ethical and appropriate manner. Ethical relationships with healthcare professionals are critical to our company's success and reputation. Our Company values are built upon the foundation of integrity and putting patients first. By appropriately sharing information, promoting dialogue with physicians and teaching hospitals, and being transparent about those interactions, we ensure that we live up to our Company values.

FAQs:

Q: What is the Sunshine Act?

A: The Physician Payments Sunshine Act ("Sunshine Act"), also known as the Open Payments Program, is a US law that requires biopharmaceutical companies and other applicable manufacturers to report transfers of value made to physicians and teaching hospitals to the Centers for Medicare & Medicaid Services (CMS) on an annual basis.

The information reported is made available to the public by way of an online searchable database managed by CMS. The Sunshine Act applies to all physicians who have an active US medical license, regardless of specialty.

Some of the types of activities with transfers of value that must be reported are consulting services, meals, honoraria, research funding, and grants. Other interactions involving transfers of value that could be subject to Sunshine Act reporting include medical journal reprints, speaking engagements, and textbooks—all of which help educate physicians and allow them to stay current on new treatments, studies, and emerging safety information.

Q: Who is subject to reporting under the Sunshine Act/Open Payments?

A: Under the Sunshine Act/Open Payments, the following are considered "covered recipients," where transfers of value provided to them by applicable manufacturers are subject to reporting to the Centers for Medicare and Medicaid Services (CMS) on an annual basis:

Physicians: Any of the following types of professionals that are legally authorized to practice in the United States, regardless of whether they are Medicare, Medicaid, or Children's Health Insurance Program (CHIP) providers and even if they are not actively practicing medicine or seeing or treating patients:

- Doctor of Medicine
- Doctor of Osteopathy
- Doctor of Dentistry
- Doctor of Dental Surgery
- Doctor of Podiatry
- Doctor of Optometry
- Doctor of Chiropractic Medicine

Teaching Hospitals: Any hospitals that received payment for Medicare direct Graduate Medical Education (GME), Inpatient Prospective Payment System (IPPS), Indirect Medical Education (IME), or Psychiatric Hospital IME programs during the last calendar year for which such information is available. On an annual basis, CMS will publish a list of teaching hospitals whose payments are subject to Sunshine Act/Open Payments reporting.

Q: What is subject to Sunshine Act/Open Payments reporting?

A: Direct, and certain indirect, payments and transfers of value that companies provide to physicians and teaching hospitals must be reported, unless the payment falls into one of a small number of categories that are exempt from reporting. For example, materials intended to educate patients, such as brochures, posters, and anatomical models, are exempt from Sunshine Act/Open Payments reporting.

Applicable Manufacturers must report:

- Payments or transfers exceeding $10.00 per item, or $100.00 in the aggregate per year that are made in connection with a particular product
- Meals provided both in and out of the physician's office if the physician eats any of the food or beverages (coffee and snacks provided from the booth at a third-party conference are exempt)

Applicable Manufacturers must report (CONT.):

- Clinical reprints or reprint carriers
- Consulting fees, including payments for serving on an advisory board
- Payments for speaking engagements
- Payments related to a variety of other activities and services provided by physicians, such as consulting on product development
- Certain grants to support non-accredited educational programs or other indirect payments to third parties if the manufacturer learns within a specified period of time that the organization used any portion of the grant to pay a physician

Research is reported separately and includes payments, the transfer of product, in-kind services provided by the applicable manufacturer, or any other transfer of value in support of the research.

Q: If my compensation for services provided is issued by a third party on behalf of your company, will it still be included in the Sunshine Act/Open Payments report to CMS?

A: Yes, we must report the fee and any other transfers of value you receive as part of the services rendered even if you are paid by a third party on behalf of our company.

Q: Are payments and transfers of value to healthcare professionals (HCPs) other than US physicians such as nurses or pharmacists employed by a teaching hospital subject to reporting under the Sunshine Act/Open Payments?

A: As described in the excerpt below, from Sunshine Act FAQ 8272 published by CMS, payments and transfers of value to HCPs other than US physicians such as nurses or pharmacists employed by a teaching hospital are generally not subject to reporting under the Sunshine Act/Open Payments:

CMS Frequently Asked Question 8272: *"If an employee (non-physician) of a teaching hospital receives a transfer of value such as a meal, would that transfer of value need to be reported as a transfer of value to the teaching hospital? Similarly, if employees of a physician's office receive a transfer of value, will that transfer of value need to be reported as a transfer of value to the physician?*

CMS Answer: *Non-physician employees of a teaching hospital are not covered recipients for the purposes of Open Payments. Accordingly, payments or other transfers of value made to these non-physician employees generally do not need to be reported...."*

However, payments to registered nurses and other non-physician HCPs may be subject to state disclosure or limitation laws depending on the state where the professional is licensed (eg Massachusetts, Minnesota, and Vermont).

Q: When do companies need to collect and report information to CMS? When will CMS make the information publicly available?

A: Companies are required to collect information for Sunshine Act/Open Payments reporting from January through December of each year, and must then report information to CMS by March 31 of each year. CMS publishes Sunshine Act/Open Payments data on an annual basis by June 30 in addition to periodic updates to the published data.

Q: Will I have a chance to review my information prior to reporting and when will it be available?

A: CMS offers a 45-day timeframe during which covered recipients have an opportunity to 1) review the payment information that applicable manufacturers reported to CMS on the CMS website, and 2) try to resolve any disputed information directly with the applicable manufacturer, before CMS makes the information public.

Q: Where will CMS report the information?

A: CMS will post the information on this publicly available, searchable website: **http://www.cms.gov/openpayments**

Resources:

Email questions to: **ethicalexchange@takeda.com**

Centers for Medicare & Medicaid Services (CMS) – Sunshine Act/Open Payments website:

- **http://www.cms.gov/openpayments**

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