

**CORPORATE INTEGRITY AGREEMENT  
BETWEEN THE  
OFFICE OF INSPECTOR GENERAL  
OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND  
DAIICHI SANKYO, INC.**

**I. PREAMBLE**

Daiichi Sankyo, Inc. (Daiichi) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements) and with the statutes, regulations, and written directives of the Food and Drug Administration (FDA requirements).

Contemporaneously with this CIA, Daiichi is entering into a Settlement Agreement with the United States. Daiichi is also entering into settlement agreements with various states (State Settlement Agreements) and Daiichi's agreement to this CIA is a condition precedent to those agreements.

Prior to the Effective Date of this CIA, Daiichi established a Compliance Program. Daiichi shall continue its Compliance Program throughout the term of this CIA and shall do so in accordance with the terms set forth below. Daiichi may modify its Compliance Program as appropriate, but, at a minimum, Daiichi shall ensure that during the term of this CIA, it shall comply with the obligations set forth herein.

**II. TERM AND SCOPE OF THE CIA**

A. The compliance obligations assumed by Daiichi under this CIA shall commence on the Effective Date of this CIA and endure for five (5) Reporting Periods, as described in this paragraph. The "Effective Date" shall be the date on which the final signatory of this CIA executes this CIA. The first "Reporting Period" shall be the period beginning on the Effective Date of this CIA and ending on March 31, 2016. Each one-year period subsequent to the first Reporting Period, beginning with the one-year period commencing April 1, 2016, shall be referred to as a "Reporting Period."

B. Sections VII, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) Daiichi's final Annual Report; or (2) any additional materials submitted by Daiichi pursuant to OIG's request, whichever is later.

C. The scope of this CIA shall be governed by the following definitions:

1. "Covered Persons" includes:

a. all owners of Daiichi who are natural persons (other than shareholders who: (i) have an ownership interest of less than 5% and (ii) acquired the ownership interest through public trading) and all officers and directors of Daiichi;

b. all employees of Daiichi who are engaged in or who supervise personnel who are engaged in Covered Functions (as defined below in Section II.C.6); and

c. all contractors, subcontractors, agents, and other persons who perform any of the Covered Functions on behalf of Daiichi, and in that capacity either: (i) interact directly with healthcare professionals (HCPs), healthcare institutions (HCIs), or consumers; or (ii) perform activities, provide services, or create materials relating to the Covered Functions and those activities, services, or materials are not reviewed or supervised by a Daiichi employee who is a Covered Person prior to execution or dissemination.

Notwithstanding the above, the term Covered Persons does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours during a Reporting Period, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during the Reporting Period.

2. "Relevant Covered Persons" includes all Covered Persons who engage in any of the Covered Functions and all individuals who supervise Covered Persons who engage in any of the Covered Functions.

3. "Government Reimbursed Products" refers to all Daiichi products that are: (a) marketed or sold by Daiichi in the United States (or pursuant to contracts with the United States) and (b) reimbursed by Federal health care programs.

4. The term “Promotional Functions” includes: (a) the selling, detailing, marketing, advertising, promoting, or branding of Government Reimbursed Products; and (b) the preparation or external dissemination of promotional materials or information about, or the provision of promotional services relating to, Government Reimbursed Products, including those functions relating to Daiichi’s review and approval processes for promotional materials and any applicable review committee(s).

5. The term “Product Related Functions” includes: (a) the preparation or external dissemination of non-promotional materials that are governed by Federal healthcare program and/or FDA requirements and distributed to HCPs, HCIs, and Payors, as defined below in Section II.C.10, about Government Reimbursed Products, including those functions relating to any applicable review committees and those functions relating to medical affairs services or involved in scientific exchange; (b) contracting with HCPs licensed in the United States or with HCIs to conduct post-marketing clinical trials, Investigator-Sponsored Studies (ISSs), and any other types of post-marketing studies relating to Government Reimbursed Products; (c) authorship, publication, and disclosure of articles or study results relating to Government Reimbursed Products; and (d) activities related to the submission of information about Government Reimbursed Products to compendia (such as Drugdex or other CMS-recognized compendia of information about Government Reimbursed Products).

6. The term “Covered Functions” refers to “Promotional Functions,” and/or “Product Related Functions,” collectively.

7. The term “Third Party Educational Activity” shall mean any scientific, educational, or professional program, meeting, or event for HCPs conducted by a third party and supported by Daiichi, including but not limited to, continuing medical education (CME), disease awareness, or sponsorship of symposia at medical conferences.

8. The term “Third Party Personnel” shall mean personnel who perform Promotional Functions or Product Related Functions who are employees of entities with which Daiichi has or may in the future (during the term of this CIA) enter into agreements to co-promote a Government Reimbursed Product in the United States or to engage in joint promotional activities in the United States relating to such a product. Daiichi has represented that: (a) Third Party Personnel are employed by entities other than Daiichi; (b) Daiichi does not control the Third Party Personnel; and (c) it would be commercially impracticable to compel the compliance of Third Party Personnel with the requirements set forth in this CIA. Daiichi agrees to promote compliance by Third Party Personnel with Federal health care program and FDA requirements by complying with the provisions set forth below in Sections III.B.2, V.A.7, and V.B.6. Provided that Daiichi complies with the requirements of Sections III.B.2, V.A.7, and V.B.6, Daiichi

shall not be required to fulfill the other CIA obligations that would otherwise apply to Third Party Personnel who meet the definition of Covered Persons.

9. (a) The term “Daiichi Affiliate(s)” shall mean any entity, other than Daiichi Sankyo, Inc., that is owned or controlled directly or indirectly, by Daiichi Sankyo Co., Ltd. and whose employees or contractors perform any Covered Functions. All obligations set forth in Section III below apply to the Covered Functions performed by the Daiichi Affiliate(s) and all references to “Daiichi” in the defined terms set forth in this Section II shall mean Daiichi and Daiichi Affiliate(s). In addition, the notice requirements in Section IV and the certification obligations set forth in Section V.C. below shall apply to both Daiichi and any Daiichi Affiliate(s).

(b) Notwithstanding the requirements of Section II.C.9(a) above, for a period of 120 days following the Effective Date, the obligations of this CIA applicable to Daiichi Affiliates shall not apply to Luitpold Pharmaceuticals, Inc. and its operating subsidiaries (Luitpold), based on Daiichi’s representations that: (i) Luitpold is not controlled directly or indirectly by Daiichi; (ii) Luitpold operates pursuant to its own separate compliance program; and (iii) given the foregoing, it is impracticable to obtain Luitpold’s compliance with the applicable Daiichi Affiliate CIA obligations on or before the Effective Date.

10. The term “Payors” shall mean entities that provide a drug health benefit program for Government Reimbursed Products, including but not limited to government payors (e.g., Medicaid and Medicare) or individuals or entities under contract with or acting on behalf of government payors and commercial health plans.

### **III. CORPORATE INTEGRITY OBLIGATIONS**

Daiichi shall establish and maintain a Compliance Program that includes the following elements:

#### **A. Compliance Responsibilities of Certain Daiichi Employees and the Board of Directors.**

1. *Compliance Officer.* Since prior to the Effective Date, Daiichi has had in place an individual to serve as its Chief Compliance Officer. Daiichi shall maintain a Compliance Officer for the term of the CIA who fulfills, at a minimum, the obligations set forth in this CIA. The Compliance Officer is and shall continue to be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program and FDA requirements. The Compliance Officer is and shall remain a

member of senior management of Daiichi; reports and shall continue to report directly to the Executive Chairman and President of Daiichi; shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Daiichi; and shall be authorized to report on such matters to the Board of Directors at any time. Written documentation of the Compliance Officer's reports to the Board of Directors shall be made available to OIG upon request. The Compliance Officer is not and shall not be, or be subordinate to, the General Counsel or Chief Financial Officer or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for Daiichi. The Compliance Officer is and shall remain responsible for monitoring the day-to-day compliance activities engaged in by Daiichi as well as for any reporting obligations created under this CIA. Any job responsibilities of the Compliance Officer unrelated to compliance shall be limited and must not interfere with the Compliance Officer's ability to perform the duties outlined in this CIA.

Daiichi shall report to OIG, in writing, any change in the identity or position description of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within five days after such a change.

2. *Compliance Committee.* Since prior to the Effective Date, Daiichi has had in place a Compliance Committee that assists the Compliance Officer in the implementation and enhancement of Daiichi's Compliance Program. Daiichi shall maintain the Compliance Committee during the term of this CIA, and at a minimum, the Compliance Committee shall meet the Compliance Committee obligations set forth in this CIA. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as sales, marketing, legal, medical affairs, regulatory affairs, research and development, human resources, audit, and finance). The Compliance Officer shall chair the Compliance Committee. The Compliance Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of Daiichi's risk areas and shall oversee monitoring of internal and external audits and investigations). The Compliance Committee shall meet at least quarterly. The minutes of the Compliance Committee meetings shall be made available to OIG upon request.

Daiichi shall report to OIG, in writing, any changes in the composition of the Compliance Committee, or any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

3. *Board of Directors Compliance Obligations.* The Board of Directors (or a committee of the Board) of Daiichi (Board) shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA. The Board must include an independent (i.e., non-executive) member.

The Board shall, at a minimum, be responsible for the following:

- a. meeting at least quarterly to review and oversee Daiichi's Compliance Program, including but not limited to the performance of the Compliance Officer and Compliance Committee; and
- b. for each Reporting Period of the CIA, adopting a resolution, signed by each individual member of the Board, summarizing its review and oversight of Daiichi's compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA.

At minimum, the resolution shall include the following language:

“The Board of Directors has made a reasonable inquiry into the operations of Daiichi's Compliance Program during the preceding twelve-month period including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, Daiichi has implemented an effective Compliance Program to meet Federal health care program requirements, FDA requirements, and the obligations of the Corporate Integrity Agreement.”

If the Board is unable to provide such a conclusion in the resolution, the Board shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement an effective Compliance Program at Daiichi.

Daiichi shall report to OIG, in writing, any changes in the composition of the Board, or any actions or changes that would affect the Board's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

4. *Management Accountability and Certifications:* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Daiichi officers or employees (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable

Daiichi business unit is compliant with applicable Federal health care program and FDA requirements and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: Executive Chairman and President of Daiichi; President, U.S. Commercial; Vice President Marketing and Access Strategy; Vice President Managed Markets and Key Account Management; Vice President Sales; Vice President Medical Affairs; Vice President Business Development and New Product Planning; Vice President Supply Chain and Technical Operations; Senior Vice President External Scientific Affairs; Executive Vice President Global Head of Development ; and, to the extent that a Daiichi business unit performs Covered Functions and is not covered by the certifications of one of the above-listed individuals, such other Daiichi executives, vice-presidents, or leaders of business units as would be necessary to ensure that there is a Certifying Employee from each such business unit engaged in Covered Functions.

For each Reporting Period, each Certifying Employee shall sign a certification that states:

“I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of department or functional area], an area under my supervision. My job responsibilities include ensuring compliance with regard to the \_\_\_\_\_ [insert name of the department or functional area] with all applicable Federal health care program requirements, FDA requirements, obligations of the Corporate Integrity Agreement, and Daiichi policies, and I have taken steps to promote such compliance. To the best of my knowledge, except as otherwise described herein, the \_\_\_\_\_ [insert name of department or functional area] of Daiichi is in compliance with all applicable Federal health care program requirements, FDA requirements, and the obligations of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by the United States.”

If any Certifying Employee is unable to provide such a certification, the Certifying Employee shall provide a written explanation of the reasons why he or she is unable to provide the certification outlined above and the steps being taken to address the issue(s) identified in the certification.

**B. Written Standards.**

1. *Code of Conduct.* To the extent not already accomplished, and within 90 days after the Effective Date, Daiichi shall update, implement, and distribute a written Code of Conduct that meets the requirements of this paragraph III.B.1 to all Covered Persons. Daiichi shall make the performance of job responsibilities in a manner

consistent with the Code of Conduct an element in evaluating the performance of all employees who are Covered Persons. The Code of Conduct shall include, at a minimum, the following:

- a. Daiichi's commitment to full compliance with all Federal health care program requirements and FDA requirements, including its commitment to comply with all requirements relating to the Covered Functions;
- b. Daiichi's requirement that all of its Covered Persons shall be expected to comply with all applicable Federal health care program requirements and FDA requirements, and with Daiichi's own Policies and Procedures;
- c. Daiichi's requirement that all Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individual designated by Daiichi, suspected violations of any Federal health care program requirements, FDA requirements, or of Daiichi's own Policies and Procedures; and
- d. the right of all individuals to use the Disclosure Program described in Section III.F, and Daiichi's commitment to non-retaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

Within 90 days after the Effective Date, each Covered Person shall certify, in writing or in electronic form, that he or she has received, read, understood, and shall abide by Daiichi's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later.

Daiichi shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. The Code of Conduct shall be distributed at least annually to all Covered Persons.

2. Third Party Personnel. Within 90 days after the Effective Date, and annually thereafter by the anniversary of the Effective Date, Daiichi shall send, electronically or in hard copy format, a letter to each entity employing Third Party Personnel. The letter shall outline Daiichi's obligations under the CIA and its commitment to full compliance with all Federal health care program and FDA requirements. The letter shall include a description of Daiichi's Compliance Program.



Daiichi shall include with the letter a copy of its Code of Conduct and shall request the entity employing Third Party Personnel to either: (a) make a copy of Daiichi's Code of Conduct and a description of Daiichi's Compliance Program available to its Third Party Personnel; or (b) represent to Daiichi that it has and enforces a substantively comparable code of conduct and compliance program for its Third Party Personnel.

3. *Policies and Procedures.* To the extent not already accomplished, and within 90 days after the Effective Date, Daiichi shall implement written policies and procedures regarding the operation of its Compliance Program, including the compliance program requirements outlined in this CIA and Daiichi's compliance with Federal health care program and FDA requirements (Policies and Procedures). At a minimum, the Policies and Procedures shall address the following:

- a. the subjects relating to the Code of Conduct identified in Section III.B.1;
- b. appropriate ways to conduct Promotional Functions in compliance with all: (i) applicable Federal healthcare program requirements, including, but not limited to the Federal Anti-Kickback Statute (codified at 42 U.S.C. § 1320a-7b(b)) and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733); and (ii) all applicable FDA requirements;
- c. appropriate ways to conduct Product Related Functions in compliance with: (i) all applicable Federal healthcare program requirements, including, but not limited to the Federal Anti-Kickback Statute (codified at 42 U.S.C. § 1320a-7b(b)) and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733); and (ii) all applicable FDA requirements;
- d. the materials and information that may be distributed by Daiichi sales representatives (including any contract sales force) about Government Reimbursed Products and the manner in which Daiichi sales representatives respond to requests for information about unapproved uses of Government Reimbursed Products. These Policies and Procedures shall require that sales representatives: (i) not engage (directly or indirectly) in improper promotion of Government Reimbursed Products (*i.e.*, sales representatives shall not promote the products for usages, dosages, length of treatment, or patient populations other than those in, or consistent with, the FDA-approved label); (ii) use only materials that have been reviewed and

approved by Daiichi; and (iii) refer all requests for information about unapproved uses of Government Reimbursed Products to Medical Affairs;

e. the materials and information that may be distributed by Medical Affairs and the mechanisms through, and manner in which, Medical Affairs receives and responds to requests for information from an HCP, HCI, or another individual or entity about unapproved uses of Government Reimbursed Products; the form and content of information disseminated by Daiichi in response to such requests; and the internal review process for the information disseminated.

The Policies and Procedures shall include a requirement that Daiichi develop a database for use by Medical Affairs (Inquiries Database) to track all requests for information about Government Reimbursed Products made to Medical Affairs. The Inquiries Database shall include the following items of information for each unique inquiry (Inquiry) received for information about Government Reimbursed Products: (i) date of Inquiry; (ii) form of Inquiry (e.g., fax, phone, etc.); (iii) name of the requesting HCP, HCI, or other individual or entity; (iv) nature and topic of request (including exact language of the Inquiry if made in writing); (v) an evaluation of whether the Inquiry relates to information about an unapproved use for the product; (vi) nature/form of the response from Daiichi (including a record of the materials provided to the HCP, HCI, or other individual or entity in response to the request); and (vii) the name of the Daiichi representative who called on or interacted with the HCP, HCI, or other individual or entity, if known;

f. the manner and circumstances under which Medical Affairs personnel interact with or participate in meetings or events with HCPs, HCIs, or Payors (either alone or with Daiichi sales representatives) and the role of the Medical Affairs personnel at such meetings or events, as well as how they handle responses to requests for information about unapproved uses of Government Reimbursed Products. These Policies and Procedures shall require that Medical Affairs personnel not engage (directly or indirectly) in the promotion of Government Reimbursed Products for unapproved uses;

g. the materials and information that may be distributed or made available by Daiichi through social media and/or direct-to-consumer

advertising. These Policies and Procedures shall be designed to ensure that Daiichi's activities in this area and the information distributed or made available comply with all applicable Federal health care program and FDA requirements, and have been reviewed and approved by the applicable Daiichi personnel before they are posted or disseminated;

h. the development, implementation, and review of call plans for sales representatives (including any contract sales force) and other Daiichi representatives who promote and sell Government Reimbursed Products. For each Government Reimbursed Product, the Policies and Procedures shall require that Daiichi review the call plans for the product and the bases upon, and circumstances under which HCPs and HCIs belonging to specified medical specialties or types of clinical practice are included in, or excluded from, the call plans. The Policies and Procedures shall also require that Daiichi modify the call plans as necessary to ensure that Daiichi is promoting Government Reimbursed Products in a manner that complies with all applicable Federal health care program and FDA requirements. The call plan reviews shall occur at least annually and shall also occur each time when the FDA approves a new or additional indication for a Government Reimbursed Product;

i. the development, implementation, and review of all plans for the distribution of samples of, or coupons or vouchers for, Government Reimbursed Products (Sample Distribution Plans). This shall include a review of the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive samples, coupons, or vouchers from Daiichi (including, separately, from sales representatives, from Medical Affairs, or through other channels). The Policies and Procedures shall also require that Daiichi modify the Sample Distribution Plans as necessary to ensure that Daiichi is promoting Government Reimbursed Products in a manner that complies with all applicable Federal health care program and FDA requirements;

j. consultant or other fee-for-service arrangements entered into with HCPs or HCIs (including but not limited to speaker programs, speaker training programs, presentations, consultant task force meetings, advisory boards, ad hoc advisory activities, and any other

financial engagement or arrangement with an HCP or HCI) and all events and expenses relating to such engagements or arrangements. These Policies and Procedures shall be designed to ensure that the arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements. The Policies and Procedures shall include requirements about the content and circumstances of such arrangements and events;

k. programs by HCPs to educate sales representatives, including but not limited to presentations by HCPs at sales meetings, preceptorships, tutorials, and experience-based learning activities. These Policies and Procedures shall be designed to ensure that the programs are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements. The Policies shall include requirements about the content and circumstances of such arrangements and events;

l. sponsorship or funding of grants (including educational grants) or charitable contributions. These Policies and Procedures shall be designed to ensure that Daiichi's funding and/or sponsorship complies with all applicable Federal health care program and FDA requirements;

m. funding of, or participation in, any Third Party Educational Activity as defined in Section II.C.7 above. These Policies and Procedures shall be designed to ensure that Daiichi's funding and/or sponsorship of such programs satisfies all applicable Federal health care program and FDA requirements.

The Policies and Procedures shall require that: (1) Daiichi disclose its financial support of the Third Party Educational Activity and, to the extent feasible with Section III.B.3.m.5 below, disclose any financial relationships with faculty, speakers, or organizers at such Activity; (2) as a condition of funding, the third party agree to disclose Daiichi's financial support of the Third Party Educational Activity and any financial relationships that Daiichi might have with faculty, speakers, or organizers at such Activity; (3) as a condition of funding, the third party require faculty, speakers, or organizers at the Third Party Educational Activity to disclose any financial relationship with Daiichi; (4) the Third Party Educational Activity

have an educational focus; (5) the content, organization, and operation of the Third Party Educational Activity (including the faculty, educational methods, materials, and venue) be independent of Daiichi's control; (6) Daiichi support only Third Party Educational Activity that is non-promotional in tone/nature; and (7) Daiichi's support of a Third Party Educational Activity shall be contingent on the provider's commitment to provide information at the Third Party Educational Activity that is fair, balanced, accurate and not misleading;

n. review of promotional, reimbursement, and disease state materials and information intended to be disseminated outside Daiichi by appropriate qualified personnel (such as regulatory, medical, and/or legal personnel) in a manner designed to ensure that legal, regulatory, and/or medical concerns are properly addressed during Daiichi's review and approval process and are elevated when appropriate. The Policies and Procedures shall be designed to ensure that such materials and information comply with all applicable Federal health care program and FDA requirements. The Policies and Procedures shall require that: (i) applicable review committees review all promotional materials prior to the distribution or use of such materials; (ii) the copy review and approval process ensure that FDA communications relevant to the product are considered and appropriately reflected in promotional materials and in a file or summary of information maintained for each product; and (iii) deviations from the standard review committee practices and protocols (including timetables for the submission of materials for review) shall be documented and referred for appropriate follow-up;

o. compensation (including through salaries, bonuses, or other means) for Relevant Covered Persons who are sales representatives and their field based managers. These Policies and Procedures shall: (i) be designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in improper promotion, sales, and marketing of Daiichi's Government Reimbursed Products; and (ii) include mechanisms, where appropriate, to exclude from incentive compensation sales that may indicate improper promotion of Government Reimbursed Products;

p. the submission of information about any Government Reimbursed Product to any CMS-recognized compendia such as

Drugdex or other published source of information used in connection with the determination of coverage by a Federal health care program for the product (hereafter “Compendia”). This includes any initial submission of information to any Compendia and the submission of any additional, updated, supplemental, or changed information (including any changes based on Daiichi’s discovery of erroneous or scientifically unsound information or data associated with the information in the Compendia and the publication of new study results.) The Policies and Procedures shall include a requirement that Daiichi conduct: (i) a review at the time of submission of information to Compendia, to verify that the information submitted to the Compendia (including information about clinical studies and other research) is complete and accurate; (ii) an annual review of all Daiichi product listings and monographs within the Compendia designed to identify errors and ensure the information is complete and accurate; and (iii) an annual review of all arrangements, processing fees, or other payments or financial support (if any) provided by Daiichi to any Compendia. Daiichi’s legal or compliance personnel shall be involved in this review; and

q. disciplinary policies and procedures for violations of Daiichi’s Policies and Procedures, including policies relating to Federal health care program and FDA requirements.

Within 90 days after the Effective Date, the Policies and Procedures shall be made available to all Covered Persons. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), Daiichi shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, any such revised Policies and Procedures shall be made available to all Covered Persons.

### C. Training and Education.

1. *General Training.* Within 90 days after the Effective Date, Daiichi shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall explain Daiichi’s:

a. CIA requirements; and

b. Compliance Program (including the Code of Conduct).

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period.

2. *Specific Training.* Within 120 days after the Effective Date, each Relevant Covered Person engaged in Promotional Functions and/or Product Related Functions shall receive at least four hours of Specific Training in addition to the General Training required above. This Specific Training shall include a discussion of:

- a. applicable Federal health care program requirements relating to Promotional Functions and/or Product Related Functions;
- b. applicable FDA requirements relating to Promotional Functions and/or Product Related Functions;
- c. Daiichi Policies and Procedures and other requirements applicable to Promotional Functions and/or Product Related Functions;
- d. the personal obligation of each individual involved in Promotional Functions and/or Product Related Functions to comply with applicable Federal health care program and FDA requirements and other applicable legal requirements;
- e. the legal sanctions for violations of the applicable Federal health care program and FDA requirements; and
- f. examples of proper and improper practices related Promotional Functions and Product Related Functions.

New Relevant Covered Persons shall receive their Specific Training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 90 days after the Effective Date, whichever is later.

After receiving the initial Specific Training described in this Section, each Relevant Covered Person shall receive at least three hours of Specific Training in each subsequent Reporting Period.

3. *Board Member Training.* Within 90 days after the Effective Date, Daiichi shall provide at least two hours of training to each member of the Board of Directors, in addition to the General Training. This training shall address the responsibilities of board members and corporate governance.

New members of the Board of Directors shall receive the Board Member Training described above within 30 days after becoming a board member or within 90 days after the Effective Date, whichever is later.

4. *Certification.* Each Covered Person who is required to complete training shall certify, in writing or in electronic form, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain these certifications, along with all course materials.

5. *Qualifications of Trainer.* Persons responsible for providing training shall be knowledgeable about the subject area of the training, including about applicable Federal health care program and FDA requirements.

6. *Update of Training.* Daiichi shall review its training annually, and, where appropriate, shall update the training to reflect changes in Federal health care program requirements, FDA requirements, any significant issues discovered during internal audits or the IRO Reviews, and any other relevant information.

7. *Computer-based Training.* Daiichi may provide the training required under this CIA through appropriate computer-based training approaches. If Daiichi chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

D. Risk Assessment and Mitigation Process. Within 120 days after the Effective Date, Daiichi shall implement a standardized, centralized annual risk assessment and mitigation process (RAMP) as further described in this Section III.D and Appendix B. The RAMP shall require compliance, legal and business unit leaders, at least annually, to evaluate and identify risks associated with each Government Reimbursed Product, including risks associated with the sales, marketing, and promotion of such products. Based on the outcomes of the risk-identification component of the RAMP, Daiichi legal, compliance and other personnel shall centrally develop and implement specific plans designed to mitigate or reduce the identified risks. The risk mitigation plans shall be developed annually and a plan shall be developed for each



Government Reimbursed Product. Daiichi shall implement the risk mitigation plans and shall track the implementation of the mitigation plans. The RAMP shall be reviewed by the IRO, and the IRO review of the process is described in more detail in Appendix B. Daiichi shall maintain the RAMP for the duration of the CIA.

E. Review Procedures.

1. *General Description.*

- a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, Daiichi shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform reviews to assist Daiichi in assessing and evaluating its Covered Functions and its RAMP. More specifically, the IRO(s) shall conduct reviews that assess Daiichi’s systems, processes, policies, procedures, and practices relating to the Covered Functions and the RAMP (collectively, “IRO Reviews”). The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.
- b. *Retention of Records.* The IRO and Daiichi shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Daiichi) related to the IRO Reviews.

2. *System, Transaction, and Additional Items Reviews.* As set forth more fully in Appendix B, the IRO Reviews shall consist of two components: Systems Reviews and Transactions Reviews relating to the Covered Functions and the RAMP. The Systems Reviews shall assess Daiichi’s systems, processes, policies, and procedures relating to the Covered Functions and the RAMP. If there are no material changes in Daiichi’s relevant systems, processes, policies, and procedures, the Systems Reviews shall be performed for the second and fourth Reporting Periods. If Daiichi materially changes its relevant systems, processes, policies, and procedures, the IRO shall perform a Systems Review for the Reporting Period in which such changes were made in addition to conducting the Systems Review for the second and fourth Reporting Periods, as set forth more fully in Appendix B.

The Transactions Reviews shall be performed annually and shall cover each of the five Reporting Periods. The IRO(s) shall perform all components of each annual Transaction Review. As set forth more fully in Appendix B, the Transactions Review shall include several components.

In addition, as set forth in Appendix B, each Transactions Review shall also include a review of up to three additional areas or practices of Daiichi identified by the OIG in its discretion (hereafter “Additional Items”). For purposes of identifying the Additional Items to be included in the Transactions Review for a particular Reporting Period, the OIG will consult with Daiichi and may consider internal audit and monitoring work conducted by Daiichi, the Government Reimbursed Product portfolio, the nature and scope of Daiichi’s promotional practices and arrangements with HCPs and HCIs, and other information known to it.

As set forth more fully in Appendix B, Daiichi may propose to the OIG that its internal audit(s) be partially substituted for one or more of the Additional Items that would otherwise be reviewed by the IRO as part of the Transactions Review. The OIG retains sole discretion over whether, and in what manner, to allow Daiichi’s internal audit and monitoring work to be substituted for any portion of the Additional Items review conducted by the IRO.

The OIG shall notify Daiichi of the nature and scope of the IRO review for each of the Additional Items not later than 150 days prior to the end of each Reporting Period. Prior to undertaking the review of the Additional Items, the IRO and/or Daiichi shall submit an audit work plan to the OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by the OIG.

3. *IRO Review Reports.* The IRO shall prepare a report based upon each IRO Review performed (IRO Review Report). Information to be included in the IRO Review Report is described in Appendices A-B.

4. *Validation Review.* In the event OIG has reason to believe that: (a) any of Daiichi’s IRO Reviews fails to conform to the requirements of this CIA; or (b) the IRO’s findings or Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the applicable IRO Review complied with the requirements of the CIA and/or the findings or Review results are inaccurate (Validation Review). Daiichi shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of Reports submitted as part of Daiichi’s final Annual Report shall be initiated no later than one year after Daiichi’s final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Daiichi of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, Daiichi may request a meeting with OIG to: (a) discuss the results of any IRO Review submissions or findings; (b) present any additional information to clarify the results of the IRO Review or to correct the inaccuracy of the IRO Review; and/or (c) propose alternatives to the proposed Validation Review. Daiichi agrees to provide any additional information as may be requested by OIG under this Section III.E.4 in an expedited manner. OIG will attempt in good faith to resolve any IRO Review issues with Daiichi prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

5. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to Daiichi a certification that the IRO has: (a) evaluated its professional independence and objectivity with respect to the reviews conducted under this Section III.E; and (b) concluded that it is, in fact, independent and objective in accordance with the requirements specified in Appendix A.

F. Disclosure Program.

Prior to the Effective Date, Daiichi established and shall maintain a Disclosure Program throughout the term of the CIA that includes a mechanism (e.g., a toll free compliance telephone line and web-based reporting system) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Daiichi's policies, conduct, practices, or procedures with respect to a Federal health care program or an FDA requirement believed by the individual to be a potential violation of criminal, civil, or administrative law. Daiichi publicizes and shall continue to appropriately publicize the existence of the Disclosure Program and the disclosure mechanism (e.g., via periodic e-mails to employees, or by posting the information in prominent common areas).

The Disclosure Program shall emphasize and shall continue to emphasize a nonretribution, nonretaliation policy and includes and shall continue to include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that it obtains all necessary information to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the

appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, Daiichi shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

Daiichi maintains and shall continue to maintain a disclosure log which includes a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews.

G. Ineligible Persons.

1. *Definitions.* For purposes of this CIA:

a. an “Ineligible Person” shall include an individual or entity who:

i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or non-procurement programs; or

ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

b. “Exclusion Lists” include:

i. the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available through the Internet at <http://www.oig.hhs.gov>); and

ii. the General Services Administration’s System for Award Management (SAM) (available through the Internet at <http://www.sam.gov>).

2. *Screening Requirements.* Daiichi shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

- a. Daiichi shall screen all prospective Covered Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Ineligible Persons.
- b. Daiichi shall screen all Covered Persons against the Exclusion Lists within 90 days after the Effective Date and thereafter shall screen against the Exclusion Lists on an annual basis .
- c. Daiichi shall maintain a policy requiring all Covered Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

Nothing in this Section III.G affects Daiichi's responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by excluded persons. Daiichi understands that items or services furnished, ordered, or prescribed by excluded persons are not payable by Federal health care programs and that Daiichi may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Daiichi meets the requirements of Section III.G.

3. *Removal Requirement.* If Daiichi has actual notice that a Covered Person has become an Ineligible Person, Daiichi shall remove such Covered Person from responsibility for, or involvement with, Daiichi's business operations related to the Federal health care programs and shall remove such Covered Person from any position for which the Covered Person's compensation is paid in whole or part, directly or indirectly, by Federal health care programs at least until such time as the Covered Person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If Daiichi has actual notice that a Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Covered Person's employment or contract term, Daiichi shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or the accuracy of any claims submitted to any Federal health care program.

#### H. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery, Daiichi shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Daiichi conducted or brought by a

governmental entity or its agents involving an allegation that Daiichi has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Daiichi shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

I. Reportable Events.

1. *Definition of Reportable Event.* For purposes of this CIA, a “Reportable Event” means anything that involves:

- a. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized;
- b. a matter that a reasonable person would consider a probable violation of FDA requirements relating to the promotion of Government Reimbursed Products, unless otherwise reported to the FDA in accordance with Section III.J below;
- c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a; or
- d. the filing of a bankruptcy petition by Daiichi.

A Reportable Event may be the result of an isolated event or a series of occurrences.

2. *Reporting of Reportable Events.* If Daiichi determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Daiichi shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists.

3. *Reportable Events under Sections III.I.1.a – III.I.1.c.* For Reportable Events under Sections III.I.1.a through III.I.1.c, the report to OIG shall include:

- a. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program and/or FDA authorities implicated;

b. a description of Daiichi's actions taken to correct the Reportable Event; and

c. any further steps Daiichi plans to take to address the Reportable Event and prevent it from recurring.

4. *Reportable Events under Section III.I.1.d.* For Reportable Events under Section III.I.1.d, the report to the OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program and/or FDA authorities implicated.

J. Notification of Communications with FDA.

Within 30 days after the date of any written report, correspondence, or communication between Daiichi and the FDA that materially discusses Daiichi's or a Covered Person's actual or potential unlawful or improper promotion of Daiichi's products, Daiichi shall provide a copy of the report, correspondence, or communication to the OIG. Daiichi shall also provide written notice to the OIG within 30 days after the resolution of any such disclosed improper promotional matter, and shall provide the OIG with a description of the findings and/or results of the matter, if any.

K. Sales Force Monitoring and Review Efforts.

Within 120 days after the Effective Date, Daiichi shall establish a comprehensive Sales Force Monitoring Program (SFMP) to evaluate and monitor its sales personnel's interactions with HCPs and HCIs. The SFMP shall be a formalized process designed to directly and indirectly observe the appropriateness of sales personnel's interactions with HCPs and HCIs and to identify potential improper promotional activities or other improper conduct. As described in more detail below, the SFMP shall include: (1) a Speaker Monitoring Program; (2) direct field observations (Observations) of sales personnel; and (3) the monitoring and review of other records relating to sales personnel's interactions with HCPs and HCIs (Records Reviews).

1. *Speaker Program Activities.* With regard to speaker programs, Daiichi has implemented a process to require all speakers to complete training and enter written agreements that describe the scope of work to be performed, the speaker fees to be paid, and compliance obligations for the speakers (including requirements regarding the use of Daiichi approved materials and requirements that speakers may not directly or indirectly promote the product for unapproved uses.) Daiichi shall establish a centralized, electronic system(s) to initiate and track all speaker programs that includes

controls designed to ensure that speaker programs are used for legitimate and lawful purposes in accordance with all applicable Federal health care program and FDA requirements. The controls shall also be designed to ensure that there is a legitimate need for the speaker programs.

Daiichi shall ensure that speakers are paid according to a centrally managed, pre-set rate structure determined based on a fair-market value analysis conducted by Daiichi (or a qualified third-party vendor on behalf of Daiichi). Daiichi shall maintain a comprehensive list of speaker program attendees through its centralized electronic system(s). In addition, Daiichi shall use its centralized electronic system(s) to handle all logistics and spending associated with speaker programs, including the tracking and review of the aggregate amount (including speaker fees, travel, and other expenses) paid to each speaker in connection with speaker programs. Daiichi shall require certifications by sales representatives or other Daiichi personnel that a speaker program complied with Daiichi requirements, or in the event of non-compliance, Daiichi shall require the identification of the policy violation and ensure appropriate follow up activity to address the violation.

Daiichi shall institute a Speaker Monitoring Program under which Daiichi compliance or other appropriately trained personnel who are independent from the functional area being monitored (Monitoring Personnel) shall attend 75 speaker programs during each Reporting Period and conduct live audits of the programs (Speaker Program Audits). The programs subject to Speaker Program Audits shall be selected using a risk-based targeting approach or a random sampling approach. For each program reviewed, Monitoring Personnel shall review slide materials and other materials used as part of the speaker program, speaker statements made during the program, and Daiichi sales representative activities during the program to assess whether the programs were conducted in a manner consistent with Daiichi's Policies and Procedures. Daiichi shall maintain the controls around speaker programs as described above and shall conduct its Speaker Program Audits as described above throughout the term of the CIA.

2. *Observations.* As a component of the SFMP, Monitoring Personnel shall conduct observations of field sales representatives (including any contract sales personnel) to assess whether the messages delivered and materials distributed to HCPs and HCIs are consistent with applicable legal requirements and with Daiichi's Policies and Procedures. These observations shall be full day ride-alongs with field sales representatives (Observations), and each Observation shall consist of directly observing all meetings between a sales representative and HCPs during the workday. The Observations shall be scheduled throughout the Reporting Period, judgmentally selected by Monitoring Personnel, include a review of each therapeutic area and actively promoted product, and be conducted across the United States.



At the completion of each Observation, Monitoring Personnel shall prepare an Observation report which includes:

- 1) the identity of the sales representative;
- 2) the identity of the Monitoring Personnel who conducted the Observation;
- 3) the date and duration of the Observation;
- 4) the product(s) promoted during the Observation;
- 5) an overall assessment of compliance with Daiichi Policies and Procedures; and
- 6) the identification of any potential improper promotional activity or other improper conduct by the field sales representative.

Monitoring Personnel shall conduct at least 30 Observations during each Reporting Period.

3. *Records Reviews.* As a component of the SFMP, Daiichi shall also review various types of records to assess field representatives' interactions with HCPs and HCIs and to identify potential or actual compliance violations. For each Reporting Period, Daiichi shall develop and implement a plan for conducting Records Reviews associated with at least three Government Reimbursed Products. The Records Reviews shall include a review of records relating to the activities of sales representatives in every separate region who promoted the products under review.

These Records Reviews shall include the monitoring and review of: (1) records and systems associated with field sales representatives' interactions with HCPs and HCIs (including records relating to speaker program activities, samples, travel and entertainment, expense reports, any payments to HCPs or HCIs, and sales communications from managers); (2) message recall studies or other similar records (such as Verbatims) purporting to reflect the details of representatives interactions with HCPs and HCIs; (3) records relating to requests for medical information about or Inquiries relating to, the Government Reimbursed Products under review; (4) call notes, or if Daiichi does not require and/or utilize call notes, the information in Daiichi's sales force automation tool that captures information about sales representatives' interactions with HCPs and HCIs and related information; (5) field sales representatives' e-mails and other electronic records; and (6) recorded results of the Observations of field sales force representatives, coaching guides, if coaching guides are required and/or used, and applicable notes or information from the sales representatives' managers.

For each sales representative reviewed, Monitoring Personnel shall complete a Records Review report that includes:

- 1) the identity of the sales representative;
- 2) the identity(ies) of the the Monitoring Personnel who conducted the records review;
- 3) the time period covered by the records review;
- 4) the Government Reimbursed Product(s) promoted by the sales representative during the records review period;
- 5) an inventory of the records from the lists above reviewed during the records review for the sales representative and the reason that any records were not reviewed (if applicable);
- 6) an assessment of compliance with Daiichi Policies and Procedures; and
- 7) the identification of any potential improper promotional activity or other improper conduct by the field sales representative.

4. *Reporting and Follow-up.* Monitoring Personnel shall have access to all relevant records and information necessary to assess field representatives' interactions with HCPs and HCIs and to identify potential or actual compliance violations. Results from the SFMP shall be compiled and reported to the Compliance Officer (or designee) for review and remediation as appropriate. Potential violations related to improper promotion of a Government Reimbursed Product or potential violations of Federal health care program or FDA requirements shall be reported to the Compliance Officer for appropriate follow-up activity. In the event that a compliance issue, including but not limited to any potential improper promotion or noncompliance with Daiichi's Policies and Procedures or legal or compliance requirements, is identified during any portion of the SFMP, Daiichi shall investigate the incident consistent with established Policies and Procedures for the handling of investigations. As part of the investigative procedures, findings shall be made and all necessary and appropriate responsive action (including disciplinary action) and corrective action shall be taken, including the disclosure of Reportable Events pursuant to Section III.I above, as applicable. Any compliance issues identified during the SFMP and any corrective action shall be recorded in the files of the Compliance Department.

Daiichi shall include a summary of the SFMP and the results of the SFMP as part of each Annual Report. As part of each Annual Report, Daiichi also shall provide the OIG with copies of the Observation report or Records Review Report for any instances in which it was determined that improper promotion occurred and a description of the action(s) that Daiichi took as a result of such determinations. Daiichi shall make all other Observation reports and Records Review reports available to the OIG upon request.

L. Monitoring of Non-Promotional Activities.

To the extent not already accomplished, within 90 days after the Effective Date, Daiichi shall develop and implement a monitoring program for the following types of activities: (1) consultant arrangement activities; and (2) medical education grants. This program shall be referred to as the Non-Promotional Monitoring Program (NPMP).

1. *Consulting Arrangement Activities.* To the extent that Daiichi engages U.S.-based U.S.-licensed HCPs for services other than for speaker programs, research-related activities, or publication activities that relate to Promotional Functions or to Product Related Functions (e.g., as a member of an advisory board or to attend consultant meetings), such HCPs shall be referred to herein as Consultants. Daiichi shall require all Consultants to enter written agreements describing the scope of work to be performed, the consultant fees to be paid, and compliance obligations for the Consultants. Consultants shall be paid according to a centrally managed, pre-set rate structure that is determined based on a fair-market value analysis conducted by Daiichi (or a qualified third-party vendor on behalf of Daiichi).

To the extent not already accomplished and within 90 days after the Effective Date, Daiichi shall establish a process to develop an annual engagement plan that identifies the business needs for, and the estimated numbers of, the various Consultant engagements and activities to occur during the following year. The annual Consultant engagement plan shall also identify the budgeted amounts to be spent on Consultant-related activities. Daiichi compliance personnel shall be involved in the review and approval of such plans, including any subsequent modification of an approved plan. The purpose of this review shall be to ensure that Consultant arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements and Daiichi Policies and Procedures.

To the extent not already accomplished and within 90 days after the Effective Date, Daiichi shall establish a process to ensure that a needs assessment has been completed to justify the retention of a Consultant prior to the retention of the Consultant. The needs assessment shall identify the business need for the retention of the Consultant and provide specific details about the consulting arrangement (e.g., information about the numbers and qualifications of the HCPs to be engaged, the agenda for the proposed meeting, and a description of the proposed work to be done and the type of work product to be generated). Any deviations from the Consultant budgeting plans shall be documented in the needs assessment form and shall be subject to review and approval by Daiichi compliance personnel.

Within 90 days after the Effective Date, Daiichi shall amend its policies and procedures in a manner designed to ensure that each Consultant performed the work for which the Consultant was engaged and that, as applicable, Daiichi received the work product generated by the Consultant.

Within 90 days after the Effective Date, Daiichi shall establish a Consultant Monitoring Program through which it shall conduct audits (Consultant Program Audits) of at least 30 consultant programs with HCPs during each Reporting Period. The Consultant Program Audits shall include at least 10 advisory boards and 20 professional services arrangements with HCPs. The Consultant Monitoring Program shall select Consultant arrangements for review using either a risk-based targeting approach or a random sampling approach. Monitoring Personnel shall review needs assessment documents, Consultant contracts, and materials relating to the program or work of the Consultant (including work product resulting from any program or event), in order to assess whether the programs and arrangements were conducted in a manner consistent with Daiichi's Policies and Procedures. Results from the Consultant Program Audits, including the identification of potential violations of Daiichi policies, shall be compiled and reported to the Compliance Officer (or compliance personnel designee) for review and follow up as appropriate.

2. *Medical Education Grant Activities.* Prior to the Effective Date, Daiichi established a grants management system that is the exclusive mechanism through which requestors may request or be awarded grants for independent medical education grants, other grant activities, and charitable contributions supported by Daiichi. Daiichi's sales and marketing personnel do not and shall continue to have no involvement in, or influence over, the review and approval of medical education grants or charitable contribution requests. Grant and charitable contribution requests shall be submitted through a centralized grants management system and processed in accordance with standardized, objective criteria developed by Daiichi (such as based upon the qualifications of the requestor, or the quality of the program funded by the grant.) In addition, the grants or charitable contributions shall be provided only pursuant to a written agreement with the funding recipient, and if payments to the funding recipient are consistent with the written agreement. Daiichi shall continue the grant and charitable contribution process described above (or an equivalent process) throughout the term of the CIA, and shall notify the OIG in writing at least 60 days prior to the implementation of any new system subsequent to the Effective Date.

To the extent not already accomplished and within 90 days after the Effective Date, Daiichi shall establish a Grants Monitoring Program through which it shall conduct audits for each Reporting Period of at least 30 medical education grants. The Grants Monitoring Program shall select grants for review on a risk-based targeting approach or a

random sampling approach. Monitoring Personnel shall review proposal documents (including grant requests), approval documents, contracts, payments and materials relating to the grant management system's review of the requests, and documents and materials relating to the grants and any events or activities funded through the grants in order to assess whether the activities were conducted in a manner consistent with Daiichi's Policies and Procedures. Results from the Grants Monitoring Programs, including the identification of potential violations of policies, shall be compiled and reported to the Compliance Officer (or compliance personnel designee) for review and follow-up as appropriate.

3. *Follow Up Reviews and Reporting.* In the event that a potential violation of Daiichi's Policies and Procedures or of legal or compliance requirements, including but not limited to potential improper promotion, are identified during any aspect of the NPMP, Daiichi shall investigate the incident consistent with established policies and procedures for the handling of investigations and shall take all necessary and appropriate responsive action (including disciplinary action) and corrective action, including the disclosure of Reportable Events pursuant to Section III.I above, if applicable.

Daiichi shall include a summary of the NPMP and the results of the NPMP as part of each Annual Report. As part of each Annual Report, Daiichi also shall provide the OIG with descriptions of any instances identified through the NPMP in which it was determined that improper promotion of Government Reimbursed Products occurred or the activities violated Daiichi's Policies and Procedures, and a description of the action(s) that Daiichi took as a result of such determinations. Daiichi shall make the documents relating to the NPMP available to the OIG upon request.

M. Reporting of Physician Payments.

1. *Reporting of Payment Information.* On or before March 31, 2015, and 90 days after the end of each subsequent calendar year during the term of the CIA, Daiichi shall post on its website a report of the cumulative value of the Payments provided to all Physician Covered Recipients from Daiichi during the prior applicable calendar year. Each annual report shall be easily accessible and readily searchable.

Each report posted pursuant to this Section III.M shall include a complete list of all Physician Covered Recipients to whom Daiichi made Payments in the preceding year. Each report shall be arranged alphabetically according to the Physician Covered Recipient's last name. The Payment amounts in the reports shall be reported in the actual amount paid for all Physician Covered Recipients on the report. For each Physician Covered Recipient, the applicable report shall include the following information: (i)

physician's full name; (ii) city and state that the physician has provided to Daiichi for contact purposes; and (iii) the aggregate value of the Payment(s) in the preceding year.

2. *Definitions and Miscellaneous Provisions.*

a. Daiichi shall make each annual report of Payments available on its website during the term of the CIA. Daiichi shall retain and make available to OIG, upon request, all supporting documentation, correspondence, and records related to all applicable Payments and to the annual report of Payments. Nothing in this Section III.M affects the responsibility of Daiichi to comply with (or liability for noncompliance with) all applicable Federal health care program requirements and state laws as they relate to all applicable Payments made to Physician Covered Recipients.

b. For purposes of Section III.M.1, "Payments" is defined to include all "direct or indirect payments or other transfers of value" as that term is defined in 42 U.S.C. § 1320a-7h and applicable regulations and guidance (including FAQs) published by CMS. The term Payments includes the types of payments or other transfers of value enumerated in 42 U.S.C. § 1320a-7h(a)(1)(A)(vi) and applicable regulations. The term includes all indirect payments or other transfers of value made to a Physician Covered Recipient through a third party where Daiichi requires, instructs, directs, or otherwise causes the third party to provide the Payment to the Physician Covered Recipient. The term also includes direct and indirect payments or other transfers of value provided to a third party at the request of or designated by the Daiichi on behalf of a Physician Covered Recipient.

c. For purposes of its annual website postings as described above, and only with regard to Payments made pursuant to product research or development agreements and clinical investigations as set forth in 42 U.S.C. § 1320a-7h(c)(1)(E), Daiichi may delay the inclusion of such Payments on its website listings consistent with 42 U.S.C. § 1320a-7h(c)(1)(E) and any regulations promulgated thereunder.

d. The term "Payments" does not include direct or indirect payments or others transfers of value or other items that are not included in or are excluded from the definition of "payment" or

otherwise excluded from reporting under 42 U.S.C. § 1320a-7h and applicable regulations and guidance (including FAQs) published by CMS.

e. For purposes of this Section III.M, the term “Physician Covered Recipient” is defined to include any physician, except for a physician who is a bona fide employee of Daiichi, as that term is defined in 42 U.S.C. § 1320a-7h(e)(6) and applicable regulations.

N. Other Transparency/Disclosure Initiatives.

1. *Medical Education Grants.* Within 90 days after the Effective Date, Daiichi shall begin posting on its company website the following information with respect to all medical education grants and charitable contributions: (i) the name of the recipient; (ii) the program name and a brief description of the program; and (iii) the amount of the grant or contribution. Daiichi shall post (and provide updates to) the above-described information about grants and charitable contributions on at least an annual basis throughout the term of this CIA. Daiichi shall notify the OIG in writing at least 60 days prior to any change in the substance of its policies regarding the funding of grants and healthcare donations or posting of the above-referenced information relating to such funding.

2. *Consultant Disclosure Obligations.* To the extent not already accomplished and within 90 days after the Effective Date, Daiichi shall require all Consultants to fully comply with all applicable disclosure obligations relating to their relationship with Daiichi that may be externally imposed on the Consultants based on their affiliation with formulary or Pharmacy & Therapeutics (P&T) committees or committees associated with the development of treatment protocols or standards or that are required by any HCI, medical committee, or other medical or scientific organization with which the Consultants are affiliated. Within 90 days after the Effective Date, to the extent not already accomplished, Daiichi shall amend its policies relating to Consultants to explicitly state that Daiichi requires all Consultants to fully comply with all applicable disclosure obligations relating to their relationship with Daiichi that may be externally imposed on the Consultants based on their affiliation with formulary, P&T committees, or committees associated with the development of treatment protocols or standards or that are required by any HCI, medical committee, or other medical or scientific organization with which the Consultants are affiliated. In addition, for any amendment to its contracts with Consultants and in any new contracts with Consultants entered into after 90 days following the Effective Date, Daiichi shall include an explicit requirement that the Consultants fully comply with all applicable disclosure requirements, as referenced above

in this paragraph. Daiichi shall continue these disclosure requirements throughout the term of this CIA.

3. *Authors.* To the extent not already accomplished and within 90 days following the Effective Date, Daiichi shall implement a requirement that all Authors of biomedical manuscripts must fully comply with the International Committee of Medical Journal Editors (ICMJE) criteria regarding authorship and disclosure of their relationship with Daiichi and disclose any potential conflicts of interest, including any financial or personal relationships that might be perceived to bias their work. Within 90 days after the Effective Date, to the extent not already accomplished, Daiichi shall amend its policies to explicitly state Daiichi's requirement about full disclosure by Authors consistent with ICMJE criteria and the requirements of any HCI, medical committee or other medical or scientific organization with which the Authors are affiliated. In addition, for any amendments to its contracts and/or engagement letters with Authors and in any contracts and/or engagement letters with Authors entered into after 90 days following the Effective Date, Daiichi shall include an explicit requirement that Authors disclose in their manuscripts, journal submissions, and elsewhere as appropriate or required, any potential conflicts of interest, including their financial or personal relationship with Daiichi, the names of any individuals who have provided editorial support for any manuscript or other publication, and all funding sources for the study or publication.

4. *Post-Marketing Commitments.* Within 90 days after the Effective Date, Daiichi shall post or make available information on its company website about post-marketing commitments (PMCs). The Daiichi website or links included therein shall provide access to general information about the PMC process, descriptions of ongoing Daiichi studies related to PMCs, and information about the nature and status of FDA PMCs. Daiichi shall continue to post or make available the above-described information about PMCs on its website or links included therein throughout the term of this CIA.

#### **IV. SUCCESSOR LIABILITY; CHANGES TO BUSINESS UNITS OR LOCATIONS**

A. Change or Closure of Unit or Location. In the event that, after the Effective Date, Daiichi changes locations or closes a business, business unit or location related to or engaged in any of the Covered Functions, Daiichi shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change or closure of the business, business unit, or location.



B. Purchase or Establishment of New Unit or Location. In the event that, after the Effective Date, Daiichi purchases or establishes a new business, business unit or location related to or engaged in any of the Covered Functions, Daiichi shall notify OIG at least 30 days prior to such purchase or the operation of the new business, business unit or location. This notification shall include the address of the new business, business unit or location, phone number, and fax number. Each new business, business unit or location and all Covered Persons at each new business, business unit or location shall be subject to the applicable requirements of this CIA.

C. Sale of Unit or Location. In the event that, after the Effective Date, Daiichi proposes to sell any or all of its business, business units or locations (whether through a sale of assets, sale of stock or other type of transaction) that are subject to this CIA, Daiichi shall notify OIG no later than five days after the date on which the sale of its business, business unit, or location is publicly disclosed by Daiichi. This notification shall include a description of the business, business unit or location to be sold, a brief description of the terms of the sale, and the name and contact information of the prospective purchaser. This CIA shall be binding on the purchaser of such business unit or location, unless otherwise determined and agreed to in writing by the OIG.

## V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 120 days after the Effective Date, Daiichi shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A.1, and a summary of other noncompliance job responsibilities the Compliance Officer may have;
2. the names and positions of the members of the Compliance Committee required by Section III.A.2;
3. the names of the members of the Board of Directors who are responsible for satisfying the obligations referenced in Section III.A.3;
4. the names and positions of the Certifying Employees required by Section III.A.4;
5. a copy of Daiichi's Code of Conduct required by Section III.B.1;

6. the number of Covered Persons required to complete the Code of Conduct certification required by Section III.B.1, the percentage of Covered Persons who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);

7. (a) a copy of the letter (including all attachments) required by Sections II.C.8 and III.B.2 sent to each party employing Third Party Personnel; (b) a list of all existing co-promotion and other applicable agreements with the party employing the Third Party Personnel; and (c) a description of the entities' responses to Daiichi's letter;

8. a summary of all Policies and Procedures required by Section III.B.3 (copies of such Policies and Procedures shall be made available to OIG upon request);

9. the following information regarding each type of training required by Section III.C:

a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and

b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information (including training certifications) shall be made available to OIG, upon request.

10. a description of the RAMP required by Section III.D;

11. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A; (d) a summary and description of any and all current and prior engagements and agreements between Daiichi and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to Daiichi;

12. a description of the Disclosure Program required by Section III.F;

13. a description of the process by which Daiichi fulfills the requirements of Section III.G regarding Ineligible Persons;

14. (if applicable) a certification from the Compliance Officer that to the best of his/her knowledge, information regarding Payments has been posted on Daiichi's website as required by Section III.M;

15. a list of all of Daiichi's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers;

16. a description of Daiichi's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and

17. the certifications required by Section V.C.

B. Annual Reports. Daiichi shall submit to OIG annually a report with respect to the status of, and findings regarding, Daiichi's compliance activities for each of the five Reporting Periods (Annual Report). Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee, the Board of Directors, or the group of Certifying Employees described in Sections III.A.1-III.A.4;

2. the dates of each report made by the Compliance Officer to the Board (written documentation of such reports shall be made available upon request);

3. a copy of the Board resolution required by Section III.A.3;

4. a summary of any changes or amendments to Daiichi's Code of Conduct required by Section III.B.1 and the reasons for such changes, along with a copy of the revised Code of Conduct;

5. the number of Covered Persons required to review Daiichi's Code of Conduct and complete the certifications required by Section III.B.1, the percentage of Covered Persons who have completed such certifications, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);

6. (a) a copy of the letter (including all attachments) required by Sections II.C.8 and III.B.2 sent to each party employing Third Party Personnel; (b) a list

of all existing co-promotion and other applicable agreements with the party employing the Third Party Personnel; and (c) a description of the entities' responses to Daiichi's letter;

7. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in applicable requirements);

8. the following information regarding each type of training required by Section III.C:

a. a description of the initial and annual training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and

b. the number of individuals required to complete the initial and annual training, percentage of individuals who completed the training, and an explanation of any exceptions.

A copy of all training materials and the documentation (including training certifications) supporting this information shall be available to OIG, upon request;

9. a description of the RAMP required by Section III.D, a summary of any changes to the process, and a description of the reasons for such changes;

10. a complete copy of all reports prepared pursuant to Section III.E and Appendix B along with a copy of the IRO's engagement letter;

11. Daiichi's response to the reports prepared pursuant to the reviews outlined in Section III.E and Appendix B, along with corrective action plan(s) related to any issues raised by the reports;

12. a summary and description of any and all current and prior engagements and agreements between Daiichi and the IRO (if different from what was submitted as part of the Implementation Report);

13. a certification from the IRO regarding its professional independence and objectivity with respect to Daiichi;

14. a summary of the disclosures in the disclosure log required by Section III.F that relate to Federal health care programs, FDA requirements, or

Government Reimbursed Products (the complete disclosure log shall be made available to OIG upon request);

15. any changes to the process by which Daiichi fulfills the requirements of Section III.G regarding Ineligible Persons;

16. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.H. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

17. a summary of Reportable Events (as defined in Section III.I) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;

18. a summary describing any written communication with the FDA required to have been reported pursuant to Section III.J. This summary shall include a description of each matter and the status of each matter;

19. a summary of the SFMP and the results of the SFMP required by Section III.K, including copies of the Observations for any instances in which it was determined that improper promotion occurred and a description of the action(s) that Daiichi took as a result of such determinations;

20. a summary of the NPMP and the results of the program described in Section III.L, including detailed description of any identified instances in which it was determined that the activities violated Daiichi's policies or that improper promotion of Government Reimbursed Products occurred and a description of the action(s) Daiichi took as a result of such determinations;

21. a certification from the Compliance Officer that information regarding Payments has been posted on Daiichi's website as required by Section III.M;

22. a description of all changes to the most recently provided list of Daiichi's locations (including addresses) as required by Section V.A.15; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers;

23. a description of: (i) any additional, updated, supplemental or changed information submitted to any Compendia in accordance with Section III.B.3.p; (ii) Daiichi's review of information submitted to the Compendia and Daiichi's conclusion

as to whether information submitted to the Compendia and product listings and monographs contained in the Compendia about Government Reimbursed Products are accurate and complete and do not contain any errors; and (iii) all arrangements, processing fees, and other payments or financial support (if any) with or made to any Compendia that were evaluated during the annual review described in Section III.B.3.p; and

24. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 90 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications.

1. *Certifying Employees.* In each Annual Report, Daiichi shall include the certifications of Certifying Employees as required by Section III.A.4;

2. *Compliance Officer.* In each Implementation Report and Annual Report, Daiichi shall include the following individual certifications by the Compliance Officer:

a. to the best of his or her knowledge, except as otherwise described in the report, Daiichi is in compliance with the requirements of this CIA;

b. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful;

c. Daiichi's: (i) Policies and Procedures as referenced in Section III.B.3 above; (ii) templates for standardized contracts and other similar documents; and (iii) the training materials used for purposes of Section III.C all have been reviewed by competent legal counsel and have been found to be in compliance with all applicable Federal health care program and FDA requirements. In addition, Daiichi's promotional materials containing claims or information about Government Reimbursed Products and other materials and information intended to be disseminated outside Daiichi have been reviewed by competent regulatory, medical, and/or, as appropriate, legal counsel in accordance with applicable Policies and Procedures

to ensure that legal, medical, and regulatory concerns have been addressed by Daiichi and brought to the attention of the appropriate individuals when required, and that the materials and information when finally approved are in compliance with all applicable Federal health care program and FDA requirements. If the applicable legal requirements have not changed, after the initial review of the documents listed above, only material changes to the documents must be reviewed by competent legal counsel. The certification shall include a description of the document(s) reviewed and approximately when the review was completed. The documentation supporting this certification shall be available to OIG, upon request; and

d. Daiichi's call plans for Government Reimbursed Products were reviewed at least once during the Reporting Period (consistent with Section III.B.3.h) and, for each product the call plans were found to be consistent with Daiichi's Policies and Procedures referenced above in Section III.B.3.h.

D. Designation of Information. Daiichi shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. Daiichi shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

## **VI. NOTIFICATIONS AND SUBMISSION OF REPORTS**

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:

Administrative and Civil Remedies Branch  
Office of Counsel to the Inspector General  
Office of Inspector General  
U.S. Department of Health and Human Services  
Cohen Building, Room 5527  
330 Independence Avenue, S.W.  
Washington, DC 20201  
Telephone: 202.619.2078

Facsimile: 202.205.0604

Daiichi:

Matt Allegrucci  
Vice President  
Ethics & Compliance Officer  
Daiichi Sankyo, Inc.  
2 Hilton Court  
Parsippany, NJ 07054  
Telephone: 973.944.2787  
Facsimile: 973.205.2808

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt. Upon request by OIG, Daiichi may be required to provide OIG with an electronic copy of each notification or report required by this CIA in searchable portable document format (pdf), in addition to a paper copy.

**VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS**

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine and/or request copies of Daiichi's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Daiichi's locations for the purpose of verifying and evaluating: (a) Daiichi's compliance with the terms of this CIA; and (b) Daiichi's compliance with the requirements of the Federal health care programs in which it participates and with all applicable FDA requirements. The documentation described above shall be made available by Daiichi to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, and/or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Daiichi's Covered Persons who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Daiichi shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Daiichi's Covered Persons may elect to be interviewed with or without a representative of Daiichi present.



## **VIII. DOCUMENT AND RECORD RETENTION**

Daiichi shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and to compliance with this CIA for six years (or longer if otherwise required by law) from the Effective Date.

## **IX. DISCLOSURES**

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Daiichi prior to any release by OIG of information submitted by Daiichi pursuant to its obligations under this CIA and identified upon submission by Daiichi as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Daiichi shall have the rights set forth at 45 C.F.R. § 5.65(d).

## **X. BREACH AND DEFAULT PROVISIONS**

Daiichi is expected to fully and timely comply with all of its CIA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Daiichi and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Daiichi fails to establish and implement any of the following obligations as described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. the Board's compliance obligations, including the resolution from the Board;
- d. the management accountability and certification obligations;
- e. a written Code of Conduct;
- f. written Policies and Procedures;

- g. the training of Covered Persons, Relevant Covered Persons, and Board Members;
- h. a RAMP as required in Section III.D and Appendix B;
- i. a Disclosure Program;
- j. Ineligible Persons screening and removal requirements;
- k. notification of Government investigations or legal proceedings;
- l. reporting of Reportable Events;
- m. notification of written communications with FDA as required by Section III.J;
- n. the SFMP required by Section III.K;
- o. the NPMP required by Section III.L;
- p. posting of any Payment-related information as required by Section III.M; and
- q. implementation of the other transparency/disclosure requirements described in Section III.N.

2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Daiichi fails to engage and use an IRO as required in Section III.E and Appendix B.

3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Daiichi fails to submit the Implementation Report or any Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

4. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Daiichi fails to submit any IRO Review report in accordance with the requirements of Section III.E and Appendix B.

5. A Stipulated Penalty of \$1,500 for each day Daiichi fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Daiichi fails to grant access.)

6. A Stipulated Penalty of \$50,000 for each false certification submitted by or on behalf of Daiichi as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.

7. A Stipulated Penalty of \$1,000 for each day Daiichi fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Daiichi stating the specific grounds for its determination that Daiichi has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Daiichi shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Daiichi receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1- 6 of this Section.

B. Timely Written Requests for Extensions. Daiichi may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Daiichi fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three days after Daiichi receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that Daiichi has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Daiichi of: (a) Daiichi's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, Daiichi shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event Daiichi elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Daiichi cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by OIG in the Demand Letter.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.d, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Daiichi has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA.

1. *Definition of Material Breach.* A material breach of this CIA means:

- a. repeated or flagrant violations of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- b. a failure by Daiichi to report a Reportable Event and take corrective action as required in Section III.I;
- c. a failure to engage and use an IRO in accordance with Section III.E and Appendices A and B;
- d. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
- e. a failure of the Board to issue a resolution in accordance with Section III.A.3.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Daiichi constitutes an independent basis for

Daiichi's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Daiichi has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Daiichi of: (a) Daiichi's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure.* Daiichi shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

- a. Daiichi is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;
- b. the alleged material breach has been cured; or
- c. the alleged material breach cannot be cured within the 30 day period, but that: (i) Daiichi has begun to take action to cure the material breach; (ii) Daiichi is pursuing such action with due diligence; and (iii) Daiichi has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30 day period, Daiichi fails to satisfy the requirements of Section X.D.3, OIG may exclude Daiichi from participation in the Federal health care programs. OIG shall notify Daiichi in writing of its determination to exclude Daiichi (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of Daiichi's receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Daiichi may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

#### E. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to Daiichi of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Daiichi shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an

appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Daiichi was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Daiichi shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Daiichi to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Daiichi requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:

- a. whether Daiichi was in material breach of this CIA;
- b. whether such breach was continuing on the date of the Exclusion Letter; and
- c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) Daiichi had begun to take action to cure the material breach within that period; (ii) Daiichi has pursued and is pursuing such action with due diligence; and (iii) Daiichi provided to OIG within that period a reasonable timetable for curing the material breach and Daiichi has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Daiichi, only after a DAB decision in favor of OIG. Daiichi's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Daiichi upon the issuance of an ALJ's decision in

favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Daiichi may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. Daiichi shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Daiichi, Daiichi shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

## **XI. EFFECTIVE AND BINDING AGREEMENT**

Daiichi and OIG agree as follows:

A. This CIA shall become final and binding on the date the final signature is obtained on the CIA.

B. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA.

C. The undersigned Daiichi signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatories represent that they are signing this CIA in their official capacity and that they are authorized to execute this CIA.

D. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

**ON BEHALF OF DAIICHI**

*/Joseph Kenneth Keller/*

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JOSEPH KENNETH KELLER  
PRESIDENT, U.S. COMMERCIAL  
DAIICHI SANKYO, INC.

1-6-15

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DATE

*/Wendy Goldstein/*

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WENDY GOLDSTEIN  
Cooley LLP  
Counsel for Daiichi

1-7-15

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DATE



**ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL  
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES**

/Robert K. DeConti/  
\_\_\_\_\_

1/7/15  
\_\_\_\_\_

ROBERT K. DECONTI  
Assistant Inspector General for Legal Affairs  
Office of Inspector General  
U. S. Department of Health and Human Services

DATE

/Keshia B. Thompson/  
\_\_\_\_\_

1/7/15  
\_\_\_\_\_

KESHIA B. THOMPSON  
Senior Counsel  
Office of Inspector General  
U. S. Department of Health and Human Services

DATE

## APPENDIX A

### INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.E of the CIA.

#### A. IRO Engagement

1. Daiichi shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives the information identified in Section V.A.11 of the CIA or any additional information submitted by Daiichi in response to a request by OIG, whichever is later, OIG will notify Daiichi if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Daiichi may continue to engage the IRO.

2. If Daiichi engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, Daiichi shall submit the information identified in Section V.A.11 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by Daiichi at the request of OIG, whichever is later, OIG will notify Daiichi if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Daiichi may continue to engage the IRO.

#### B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the IRO Reviews who have expertise in the pharmaceutical industry and have expertise in all applicable Federal health care program and FDA requirements relating to Covered Functions and the RAMP, including but not limited to expertise relating to marketing and promotional activities associated with pharmaceutical products. The assigned individuals shall also be experienced in risk identification and mitigation in relation to pharmaceutical product marketing and promotion. The assigned individuals shall also be knowledgeable about the general requirements of the Federal health care program(s) under which Government Reimbursed Products are reimbursed;

2. assign individuals to design and select the sample for the Transaction Reviews who are knowledgeable about the appropriate statistical sampling techniques; and

3. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities

The IRO shall:

1. perform each IRO Review in accordance with the specific requirements of the CIA;

2. follow all applicable Federal health care program and FDA requirements in making assessments in each IRO Review;

3. if in doubt of the application of a particular Federal health care program or FDA requirement, policy or regulation, request clarification from the appropriate authority (*e.g.*, CMS or FDA);

4. respond to all OIG inquiries in a prompt, objective, and factual manner; and

5. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. IRO Independence and Objectivity

The IRO must perform each IRO Review in a professionally independent and objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist between the IRO and Daiichi.

E. IRO Removal/Termination

1. *Provider and IRO.* If Daiichi terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, Daiichi must submit a notice explaining its reasons for termination or the reason for withdrawal to OIG no later than 30 days after termination or withdrawal. Daiichi must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the IRO.

2. *OIG Removal of IRO.* In the event OIG has reason to believe the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require Daiichi to engage a new IRO in accordance with Paragraph A of this Appendix. Daiichi must engage a new IRO within 60 days of termination of the IRO.

Prior to requiring Daiichi to engage a new IRO, OIG shall notify Daiichi of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, Daiichi may present additional information regarding the IRO's qualifications, independence or performance of its responsibilities. OIG will attempt in good faith to resolve any differences regarding the IRO with Daiichi prior to requiring Daiichi to terminate the IRO. However, the final determination as to whether or not to require Daiichi to engage a new IRO shall be made at the sole discretion of OIG.

**Appendix B to CIA  
for  
Daiichi Sankyo, Inc.  
IRO Reviews**

**I. IRO Engagement, General Description**

As specified more fully below, Daiichi shall retain an Independent Review Organization(s) (IRO) to perform engagements to assist Daiichi in assessing and evaluating certain of its systems, processes, policies, and procedures related to Daiichi's Covered Functions and RAMP (IRO Review). The IRO Review shall consist of two components - a systems review (the Covered Functions and RAMP Review) and a transactions review (the IRO Transactions Review), as described more fully below. Daiichi may engage, at its discretion, a single entity to perform both components of the IRO Review, provided that the entity has the necessary expertise and capabilities to perform both.

If there are no material changes in Daiichi's systems, processes, policies, and procedures relating to Covered Functions or its RAMP, the IRO shall perform the Systems Review for the second and fourth Reporting Periods. If Daiichi materially changes its systems, processes, policies, and procedures relating to Covered Functions or its RAMP, the IRO shall perform a Systems Review for the Reporting Period(s) in which such changes were made in addition to conducting the Review for the second and fourth Reporting Periods. The additional Systems Review(s) shall consist of: 1) an identification of the material changes; 2) an assessment of whether other systems, processes, policies, and procedures previously reported did not materially change; and 3) a review of the systems, processes, policies, and procedures that materially changed. The IRO shall conduct the Transactions Review for each Reporting Period of the CIA.

**II. IRO Systems Review**

The Covered Functions and RAMP Systems Review shall be a review of Daiichi's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to certain Covered Functions and its RAMP. Where practical, Daiichi personnel may compile documentation, schedule and organize interviews, and undertake other efforts to assist the IRO in performing the Systems Review. The IRO is not required to undertake a de novo review of the information gathered or activities undertaken by Daiichi pursuant to the preceding sentence. Specifically, the IRO shall review Daiichi's systems, processes, policies, and procedures associated with the following (hereafter "Reviewed Policies and Procedures"):

- 1) Daiichi's systems, processes, policies, and procedures relating to incentive compensation for Relevant Covered Persons who are sales representatives and field-based managers of sales representatives, with regard to whether the systems, policies, processes, and procedures are designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in the improper promotion, sales, and marketing of Daiichi's products. This shall include a review of the bases upon which compensation is determined and the extent to which compensation is based on product performance. To the extent that Daiichi establishes different systems, processes, policies, or procedures relating to compensation for different products, the IRO shall review each type of compensation arrangement separately;
- 2) Daiichi's systems, processes, policies, and procedures relating to the development and review of call plans (as described in Section III.B.3.h of the CIA). This shall include a review of the bases upon which HCPs and HCIs belonging to specified medical specialties are included in, or excluded from, the call plans based on, among other factors, expected utilization of products for FDA-approved uses or non-FDA-approved uses;
- 3) Daiichi's systems, processes, policies, and procedures relating to sample distribution. This shall include a review of the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive samples from Daiichi (including, separately, from Daiichi sales representatives, from Medical Affairs, or through other channels). It shall also include a review of whether samples of Government Reimbursed Products are distributed by Daiichi through sales representatives or are distributed from a central location and the rationale for the manner of distribution;
- 4) Daiichi's systems (including any centralized electronic system), processes, policies, and procedures relating to speaker programs, speaker training programs, and all events and expenses relating to such engagements or arrangements;
- 5) Daiichi's systems, processes, policies, and procedures relating to non-speaker related consultant or other fee-for-service arrangements entered into with HCPs or HCIs (including, but not limited to, presentations, consultant task force meetings, advisory boards, preceptorships, mentorships (if any), and ad hoc advisory activities, and any other financial engagement or arrangement with an HCP or HCI) and all events and expenses relating to such engagements or arrangements;
- 6) Daiichi's systems, processes, policies and procedures relating to the submission of information about any product to any CMS-recognized compendia such as Drugdex or other published source of information used in connection with the determination of coverage by a Federal health care program for the Product ("Compendia"). This includes

any initial submission of information to any Compendia and the submission of any additional, updated, supplemental, or changed information, (*e.g.*, any changes based on Daiichi's discovery of erroneous or scientifically unsound information or data associated with the information in the Compendia.) The review shall also assess Daiichi's processes relating to its annual review of all arrangements with, and processing fees or other payments or financial support (if any) provided by the company to any Compendia;

7) Daiichi's systems, processes, policies and procedures relating to the RAMP, including but not limited to, a review of the: (i) the sources and types of information used in connection with the risk assessment (*e.g.*, the individual personnel, departments or functional areas, and/or any data and systems involved); (ii) the timing for development of the risk assessment and risk mitigation plans;

8) An assessment of whether, in developing the risk assessment or risk mitigation plans: (i) additional or different sources of information should be utilized; (ii) additional or different types of data or information should be utilized; and (iii) additional or different timing cycles should be utilized;

9) A review of the experience and background of personnel responsible for the development of the risk assessment and risk mitigation plans; and an assessment of the completeness and appropriateness of the relevant training, policies, procedures, standard operating procedures, and guidance each such individual receives;

10) An assessment of whether risk monitoring and audit activities related to RAMP: (i) adequately identify potential risks; (ii) adequately monitor all relevant identified risks; (iii) identify any actual problems that have occurred in connection with the identified potential risk; and/or (iv) prevent reoccurrence of any problems associated with an identified risk;

11) An assessment of whether risk monitoring and audit activities related to Daiichi's RAMP should be: (i) enhanced, revised, or refined; (ii) changed to include additional or different mitigation/monitoring options to be considered based upon specific identified risks; and/or (iii) tracked and reviewed more frequently than prescribed by current policies to ensure that the options address all relevant risks for the specific Daiichi products reviewed; and

12) A review of the systems, policies, procedures, and processes by which Daiichi tracks and manages RAMP activities and an assessment of whether the systems, policies, procedures and processes ensure that risk mitigations plans are appropriately implemented (including by identifying individuals responsible for the follow-up action items).

### III. IRO Systems Review Report

The IRO shall prepare a report based upon each Systems Review. For each of the Reviewed Policies and Procedures identified in Section II. above, the report shall include the following items:

- 1) description of the documentation (including policies) reviewed and any personnel interviewed;
- 2) a detailed description of Daiichi's systems, policies, processes, and procedures relating to the items identified in Sections II.1-12 above, including a general description of Daiichi's control and accountability systems (*e.g.*, documentation and approval requirements, and tracking mechanisms) and written policies regarding the Reviewed Policies and Procedures;
- 3) a description of the manner in which the control and accountability systems and the written policies relating to the items identified in Sections II.1-12 above are made known or disseminated within Daiichi;
- 4) a detailed description of Daiichi's incentive compensation system for Covered Persons who are sales representatives, including a description of the bases upon which compensation is determined and the extent to which compensation is based on product performance. To the extent that Daiichi may establish compensation differently for individual products, the IRO shall report separately on each such type of compensation arrangement;
- 5) findings and supporting rationale regarding any weaknesses in Daiichi's systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures, if any;
- 6) recommendations to improve any of the systems, policies, processes, or procedures relating to the Reviewed Policies and Procedures, if any;
- 7) whether the risk monitoring and risk mitigation action associated with RAMP identify relevant risks and address identified risks;
- 8) whether sufficient controls exist to ensure that all monitoring and auditing activities and risk mitigation action items are tracked appropriately;
- 9) whether the RAMP (including the options for risk mitigation activities) potentially mitigates identified risks; and



10) whether sufficient controls exist to ensure that all agreed-upon risk monitoring and audit activities and risk mitigation action items are completed as planned pursuant to the RAMP.

#### **IV. IRO Transactions Review**

As described more fully below in Sections IV.A-C, the Transactions Review shall include: (1) a review of records relating to a sample of the Payments that are reported by Daiichi pursuant to Section III.M of the CIA; and (2) a review of up to three additional items identified by the OIG in accordance with Section III.E. of the CIA (hereafter “Additional Items”.) The IRO shall report on all aspects of its reviews in the Transactions Review Reports.

##### **A. IRO Review of Physician Payment Listings**

###### **1. Information Contained in Physician Payment Listings**

As set forth in Section III.M of the CIA, Daiichi shall post annual reports of Physician Covered Recipients who received Payments, as defined in the CIA, directly or indirectly from Daiichi. For each Physician Covered Recipient, each report shall include the following information: (i) physician’s full name; (ii) city and state of the physician’s practice; and (iii) the aggregate value of the Payment(s) in the preceding calendar year.

For purposes of this IRO review, the term “Control Documents” shall include all documents or electronic records associated with each Payment reflected in the report for the sampled Physician Covered Recipient. For example, the term “Control Documents” includes, but is not limited to, documents relating to the nature, purpose, and amount of all Payments reflected in the report; contracts relating to the Payment(s) reflected in the report; documents relating to the occurrence of Payment(s) reflected in the report; documents reflecting any work product generated in connection with the Payment(s); documents submitted by sales representatives or headquarters personnel to request approval for the Payment(s); and business rationale or justification forms relating to the Payment(s).

###### **2. Selection of Sample for Review**

For each Reporting Period, the OIG shall have the discretion to identify up to 50 Physician Covered Recipients from the applicable report that will be subject to the IRO review described below. If the OIG elects to exercise this discretion, it shall notify the IRO of the Physician Covered Recipients subject to the IRO review.

If the OIG elects not to exercise its discretion as described above, the IRO shall randomly select 50 Physician Covered Recipients to be included in the review. For each selected Physician Covered Recipient, the IRO shall review the entry in the report and the Control Documents relating to Payments reflected in the report identified by the IRO as necessary and sufficient to validate the Payment information in the report.

### 3. IRO Review of Control Documents for Sampled Physician Covered Recipients

For each Physician Covered Recipient selected as part of the sample, the IRO shall review the Control Documents identified by the IRO as necessary and sufficient to validate each Payment reflected in the report to evaluate the following:

- a) Whether Control Documents are available relating to each Payment reflected in the report for the sampled Physician Covered Recipient;
- b) Whether the Control Documents were completed and archived in accordance with the requirements set forth in Daiichi's policies;
- c) Whether the aggregate value of the Payment(s) as reflected in the report for the sampled Physician Covered Recipient is consistent with the value of the Payment(s) reflected in the Control Documents; and
- d) Whether the Control Documents reflect that Daiichi's policies were followed in connection with Payment(s) reflected in the report (*e.g.*, all required written approvals for the activity were obtained in accordance with Daiichi's policies.)

### 4. Identification of Material Errors and Additional Review

A Material Error is defined as any of the following:

- a) A situation in which all required Control Documents relating to Payments reflected in the report for the sampled Physician Covered Recipient do not exist and:
  - i. no corrective action was initiated prior to the selection of the sampled Physician Covered Recipients; or
  - ii. the IRO cannot confirm that Daiichi otherwise followed its policies and procedures relating to the entry in the report for the sampled Physician Covered Recipient, including its policies and procedures relating to any Payment(s) reflected in the report; or

b) Information or data is omitted from key fields in the Control Documents that prevents the IRO from assessing compliance with Daiichi's policies and procedures, and the IRO cannot obtain this information or data from reviewing other Control Documents.

If a Control Document does not exist, but Daiichi has initiated corrective action prior to the selection of the sampled Physician Covered Recipient, or if a Control Document does not exist but the IRO can determine that Daiichi otherwise followed its policies and procedures with regard to each entry in the report for a sampled Physician Covered Recipient, the IRO shall consider such a situation to be an exception (rather than a Material Error) and the IRO shall report the situation as such. Similarly, the IRO shall note as exceptions any Control Documents for which non-material information or data is omitted.

If the IRO identifies any Material Errors, the IRO shall conduct such Additional Review of the underlying Payment associated with the erroneous Control Documents as may be necessary to determine the root cause of the Material Errors. For example, the IRO may need to review additional documentation and/or conduct interviews with appropriate personnel to identify the root cause of the Material Error(s) discovered.

#### B. IRO Review of Additional Items

As set forth in Section III.E. of the CIA, for each Reporting Period, the OIG at its discretion may identify up to three additional items for the IRO to review (hereafter "Additional Items".) No later than 150 days prior to the end of the applicable Reporting Period, the OIG shall notify Daiichi of the nature and scope of the IRO review to be conducted for each of the Additional Items. Prior to undertaking the review of the Additional Items, the IRO and/or Daiichi shall submit an audit work plan to the OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by the OIG. The IRO shall include information about its review of each Additional Item in the Transactions Review Report (including a description of the review conducted for each Additional Item; the IRO's findings based on its review for each Additional Item; and the IRO's recommendations for any changes in Daiichi's systems, processes, policies, and procedures based on its review of each Additional Item.)

Daiichi may propose to the OIG that its internal audit(s) and/or reviews conducted as part of the Sales Force Monitoring Program (SFMP) described in Section III.K of the CIA or the Non-Promotional Monitoring Program (NPMP) described in Section III.L of the CIA be substituted for one or more of the Additional Items that would otherwise be reviewed by the IRO for the applicable Reporting Period. The OIG retains sole discretion over whether, and in what manner, to allow Daiichi's internal audit work and monitoring

activities to be substituted for a portion of the Additional Items review conducted by the IRO.

In making its decision, the OIG agrees to consider, among other factors, the nature and scope of Daiichi's planned monitoring activities and internal audit work, the results of the Transactions Review(s) during prior Reporting Period(s), and Daiichi's demonstrated audit capabilities to perform the proposed audit work internally. If the OIG denies Daiichi's request to permit its monitoring activities or internal audit work to be substituted for a portion of the IRO's review of Additional Items in a given Reporting Period, Daiichi shall engage the IRO to perform the Review as outlined in this Section IV.

If the OIG agrees to permit certain of Daiichi's monitoring activities or internal audit work for a given Reporting Period to be substituted for a portion of Additional Items review, such internal work would be subject to verification by the IRO (Verification Review). In such an instance, the OIG would provide additional details about the scope of the Verification Review to be conducted by the IRO. However, for purposes of any Verification Review, the IRO shall review at least 20% of the sampling units reviewed by Daiichi in its internal audits.

#### C. Transactions Review Report

For each Reporting Period, the IRO shall prepare a report based on its Transactions Reviews. The report shall include the following:

##### 1) General Elements to Be Included in Report

- a) Review Objectives: A clear statement of the objectives intended to be achieved by each part of the review;
- b) Review Protocol: A detailed narrative description of the procedures performed and a description of the sampling unit and universe utilized in performing the procedures for each sample reviewed; and
- c) Sources of Data: A full description of documentation and other information, if applicable, relied upon by the IRO in performing the Transactions Review.

##### 2) Results to be Included in Report

The following results shall be included in each Transactions Review Report:

(Relating to the Physician Covered Recipient Payment Reports)

- a) a description of the entries in the report for each Physician Covered Recipient sampled and a description of Control Documents reviewed in connection with each selected Physician Covered Recipient;
- b) for each sampled Physician Covered Recipient, findings and supporting rationale as to whether: (i) all required Control Documents exist; (ii) each Control Document was completed in accordance with all of the requirements set forth in the applicable Daiichi policy; (iii) the aggregate value of the Payment(s) as reflected in the report for the sampled Physician Covered Recipient is consistent with the value of the Payment(s) reflected in the Control Documents; (iv) each Control Document reflects that Daiichi's policies were followed in connection with the underlying activity reflected in the document (*e.g.*, all required approvals were obtained); and (v) any corrective action or disciplinary action was undertaken in those instances in which Daiichi policies were not followed;
- c) for each sampled Physician Covered Recipient, an identification and description of all exceptions discovered. The report shall also describe those instances in which corrective action was initiated prior to the selection of the sampled Physician Covered Recipient, including a description of the circumstances requiring corrective action and the nature of the corrective action; and
- d) if any Material Errors are discovered, a description of each error, the Additional Review procedures performed and a statement of findings as to the root cause(s) of the Material Error;

(Relating to the Review of Additional Items)

- e) for each Additional Item reviewed, a description of the review conducted;
- f) for each Additional Item reviewed, the IRO's findings based on its review;
- g) for each Additional Item reviewed, the findings and supporting rationale regarding any weaknesses in Daiichi's systems, processes, policies, procedures, and practices relating to the Additional Item, if any; and
- h) for each Additional Item reviewed, recommendations, if any, for changes in Daiichi's systems, processes, policies, and procedures that would correct or address any weaknesses or deficiencies uncovered during the review.