
ALMIRALL, LLC

Code of Interactions with Healthcare Professionals (HCP)

Sponsor: Ron Menezes, Almirall, LLC, President & General Manager

Owner: Adriana Mosailov, Almirall, LLC, Chief Compliance Officer

Date: October 2018

ALMIRALL, LLC

Table of Contents

Introduction

1.1. Engaging healthcare professionals - Key Principles

- 1.1.1. Definition of Healthcare Professional (HCP)
- 1.1.2. Legitimate business need
- 1.1.3. HCP qualifications and Licensure status
- 1.1.4. Executed Agreement
- 1.1.5. Fair Market Value (FMV) Remuneration
- 1.1.6. Transparency and Disclosures

1.2. Types of Interactions

- 1.2.1. Scientific Exchange
 - 1.2.1.1. Almirall-Sponsored Research
 - 1.2.1.2. Investigator Sponsored Trials (ISTs)
 - 1.2.1.3. Publications
 - 1.2.1.4. Formulary and Payer Interactions
 - 1.2.1.5. Compendia
 - 1.2.1.6. Advising and Consulting
 - a. Advisory Boards
 - b. Consulting engagements
- 1.2.2. Promotional Interactions & Information sharing
 - 1.2.2.1. Call plans
 - 1.2.2.2. Promotional messages & materials. Reprints
 - 1.2.2.3. Addressing unsolicited requests for off-label information
 - 1.2.2.4. Sample distribution
 - 1.2.2.5. Expert-Led Promotional Meetings
 - a. Speaker Programs
 - b. Speaker Training
- 1.2.3. Rules of engagement between sales and medical
 - a. External Interactions
 - b. Internal Interactions
- 1.2.4. Compensation & Business Courtesy
 - 1.2.4.1. Fee for service
 - 1.2.4.2. Business meals
 - 1.2.4.3. Gifts and Entertainment

- 1.2.5. Independent Medical Education
- 1.2.6. Sponsorships and Charitable Contributions
- 1.2.7. International markets - Anti-Bribery Anti-Corruption (ABAC)

1.3. Transparency

- 1.3.1. Disclosures
- 1.3.2. Reporting

Attachments:

- A. Frequently Asked Questions (FAQs)**
- B. Employee Acknowledgement & Certification**

INTRODUCTION

Our Commitment to Ethics & Compliance

Almirall, LLC (“Almirall US” or “Company”) is dedicated to helping patients achieve their goals of healthy skin and a positive self-image. The company markets branded prescription drugs in the dermatology therapeutic area, including for conditions such as acne, steroid-responsive dermatoses, actinic keratosis, and other skin health-related conditions.

Our Company is committed to ethical conduct and integrity in our relationships with patients, the healthcare community and our business partners.

We are adopting this Code for Interactions with Healthcare Professionals (HCPs) as our compendium of principles that govern our business partnerships and relationships with physicians and other healthcare professionals in the United States, whether we engage in commercial, scientific, educational, or other activities on behalf of Almirall. We equally require and expect that those who conduct business on our behalf conform to all applicable laws, regulations and guidelines, including the obligations outlined in this Code.

Interacting with Healthcare Professionals (HCPs)

Almirall US interactions with HCPs are meant to enhance knowledge and advance science and medicine to the ultimate benefit of the patient.

Some of the common interactions that we may have with HCPs are:

- Scientific/clinical exchanges of information intended to (a) inform on the current healthcare and medical practice developments and trends impacting on our products; (b) address request(s) of information about the scientific and clinical data related to our products and/or associated disease states, (c) seek advice from qualified medical experts towards the development of scientific or commercial strategies and initiatives.
- Promotional interactions, focused on informing healthcare professionals about FDA-approved products marketed by the Company, including a fair balance of information regarding their benefits and risks, and disease states related to those therapies.
- Market Research interactions designed to obtain the healthcare community’s feed-back regarding certain business development considerations.

1.1. Engaging HCPs - Key Principles:

When interacting with HCPs, Almirall US is committed to abide by the following key principles:

Independence of the medical decisions: Our employees shall never act in a manner that could be perceived as improperly influencing decisions to prescribe, use or recommend the use of a Company product.

Transparency: Interactions between Company representatives and HCPs must be transparent, well documented and reported in compliance with all applicable laws, regulations, and relevant professional codes of conduct.

Fairness: HCPs whom we engage to perform a service for, or on behalf of the Company, are compensated for such service with a fee that is consistent with a fair market value (FMV) for such service.

Contractual Agreement: Any HCP who provides a service for Almirall must execute a written contractual agreement prior to the performance of any services for which he/she is engaged. The agreement must document: a) services sought; b) detail of how the services will be rendered; c) estimated time to delivery (d) FMV remuneration for the services provided; e) how the work product will be documented and used; and f) HCP compliance responsibilities.

1.1.1. Healthcare Professional - Definition:

Almirall US defines an HCP as any member of the medical, dental, pharmacy or nursing professions, or any other person who in the course of his or her professional activities provides healthcare services or may prescribe, recommend, purchase, supply or administer a pharmaceutical product for human patients.

Any Company representative seeking an HCP engagement must submit a request for HCP Engagement Proposal, and obtain documented approval by the Almirall US Medical Affairs Lead and the Chief Compliance Officer, prior to proceeding with the execution of a Contractual Agreement, or any other activity pertaining to such engagement.

1.1.2. Legitimate business need:

The engagement of an HCP to provide a service to the Company must be based on a well-defined and documented legitimate business need. We do not engage HCPs for the purpose of building relationships, or otherwise as means to influence prescribing decisions in a quid-pro-quo manner, such as incentivizing or rewarding the purchase, prescription, or recommendation of a Company product. Sales representatives and their direct management may offer recommendations regarding an HCP's expertise in certain circumstances, however they have no role or involvement in making decisions regarding the selection or engagement of a HCP for any service. HCPs engaged by the Company for any activity must meet pre-set selection criteria consistent with the service sought.

Our Company does not tolerate any transfers of value to its customers, including to any HCPs, beyond the legitimate, pre-approved and well-documented business interactions. Gifts (other than pre-approved educational items of minimal value) and/or any sort of entertainment for HCPs are not permitted and may not be offered at any time by any of our employees.

1.1.3. Healthcare Professional qualifications and Licensure status:

When considering the engagement of HCP expertise for any service, our representatives are required to

outline selection criteria for that legitimate need prior to considering any candidate for the service to be provided. The selected candidate must have the appropriate credentials and qualifications/expertise to fulfil the requirements of the engagement. In general, a qualified internal subject matter expert (e.g. a Medical Affairs staff member), assesses the qualifications of an HCP versus the pre-determined selection criteria and the business need, regardless of whether the engagement is for a commercial or a scientific activity.

Prior to completing an engagement, or executing a contract with any HCP, the Company shall perform a verification of that HCP's professional license to confirm that it is current and in good standing with the state of licensure, the Office of Inspection General (OIG) of

the U.S. Department of Health and Human Services (HHS), and where applicable, the Federal Food and Drug Administration (FDA). The requesting department seeking an engagement is responsible to verify and confirm that none of the HCPs selected for such engagement is excluded or disqualified to perform the activity(ies) sought.

1.1.4. Executed Agreement:

As outlined in the key principle of *Contractual Agreement* above in this section, any HCP who is engaged by Almirall US, must have a **fully executed contractual agreement in place prior to the initiation of any work or services**. Unless prior written authorization is provided by Company authorized representatives, approved contract templates shall be used for all HCP agreements. Any proposed contract amendments or revisions to such agreements must be approved in advance by a Legal or Compliance Company representative.

1.1.5. Fair Market Value Remuneration:

In all cases, HCP compensation must be based on FMV, as outlined in the Almirall US Fair Market Value (FMV) Policy. Our FMV rates result from an objective, third-party conducted analysis, and are based on national survey data for the specialty area, level of effort for the activity and the HCP's credentials, qualifications and expertise. Any requests for exceptions to the FMV rates must be well justified and documented, and are subject to review and approval by the Company Chief Compliance Officer.

In addition to a FMV fee for service compensation, HCPs may be offered business meals, travel, and lodging, as appropriate for the specific service provided and as documented in the Contractual Agreement. Incidental expenses incurred by HCPs in conjunction with the performance of contracted services (e.g., parking, tolls) may be reimbursed based on producing valid and legible receipts.

Almirall US does not compensate or reimburse for any expenses incurred on behalf of the HCP, or otherwise by any HCP guests or spouses. An exception may be sought in situations where the HCP guest or spouse met the selection criteria, is qualified in their own right, and has been selected by the Company to perform a service or participate in a legitimate activity (e.g. advisory board or consultant meeting). In those situations, a specific exemption approval must be sought from the Almirall US Chief Compliance Officer prior to executing any agreement with the HCP or the qualified guest.

1.1.6. Transparency and Disclosures:

The Federal Affordable Care Act, in its Open Payments requirement, mandates that drug and medical

device manufacturers publicly report all payments, reimbursements or other transfers of value (e.g. educational items, meals, reprints, samples, etc.) made to a licensed HCP by the company. Some state laws may impose additional reporting obligations, and some states impose certain restrictions and/or prohibitions on providing any items of value to HCPs.

All Company representatives are required to report any and all expenses and transfers of value incurred during their interactions with HCPs, and maintain detailed and accurate documentation of all interactions, including any transfers of value. In order to ensure that we maintain compliance with individual state laws and regulations, field representatives must be current with the requirements of state law in their territory and verify HCP licensure before incurring any expense with that HCP.

1.2. Types of Interactions:

1.2.1. Scientific Exchange

Communications and interactions with HCPs conducted by the medical and scientific departments of the Company are non-promotional in nature and conducted under the safe harbor protections of Scientific Exchange, as outlined by the Food and Drug Administration (FDA).

What is Scientific Exchange? The communication of objective, balanced, and substantiated scientific information constitutes scientific exchange when conducted under the jurisdiction of medical and/or scientific company staff members. Although the FDA does not define scientific exchange versus promotion in its regulations, distinguishing between the two is relevant because, according to government regulations, only certain interactions fall within the protection of safe harbor for Scientific Exchange. Characteristics of Scientific Exchange, as outlined in the regulations are:

- Exchange does not occur in a promotional context;
- Truthful and non-misleading data has to be presented fairly, with no inferences or claims that the drug has been proven to be safe or effective;
- Where presenting study results in external communications or press releases, only data points and numbers may be presented with no conclusions drawn regarding safety or efficacy;
- Disclosures are made by a “prominently affixed and clearly displayed label” stating about the unapproved nature of the drug, indication, dosage, route of administration, etc., a statement of currently approved indication(s), and the manufacturer’s role in the program;
- Comparisons are not made beyond the data results obtained during head to head clinical trials;
AND
- Discussions are carried out by members of a scientific department.

Examples of scientific exchange are:

- Presentations and discussions of study protocols
- Publication of results from scientific studies
- Scientific presentations of clinical study results at professional conferences
- Journal article and/or medical reference text in peer-reviewed publications, unedited and unabridged
- Responses to unsolicited requests for off-label information provided by a designated medical function
- Exchanges of medical and scientific information in the context of advisory and consulting activities led by medical or scientific departments

Any activity that involves, or is related in any way with product promotion, is outside the guardrails of the Scientific Exchange safe harbor, which has been defined by regulatory agencies to protect authentic and legitimate scientific communications. Company representatives who are permitted to engage in scientific communications must not be members of a commercial department or function, or involved with activities related to the sales, marketing, or promotion of an Almirall product. If you are in a commercial role you cannot and must not engage in scientific exchange regardless of your education, background and qualifications. Only representatives of the Research and Medical departments are deemed by regulators as

adequately trained and qualified to carry out such legitimate peer to peer scientific communications, some of which are outlined below for reference:

- with clinical investigators related to the design and conduct of clinical trials, to be carried out by representatives of the Research or Medical departments;
- with physicians who provide information and advice about safety events, to be carried out by representatives of the Medical and Pharmacovigilance departments;
- with HCPs who are interested to understand and inquire in an unsolicited manner about the scientific information that is at the core of our products, disease states or therapeutic areas of interest, or an off-label use of any of our products, to be carried out by representatives of the Medical Affairs department or their designees;
- with HCPs who are interested to write articles and scientific publications about our products, disease states or therapeutic areas of interest for the Company, to be carried out by representatives of the R&D and/or Medical department;
- with regulatory agencies who make inquiries about our products, product development activities, or regulatory reporting, to be carried out by representatives of the Regulatory Affairs department;
- with experts in disease states or therapeutic areas of interest to Almirall, whom we engage to provide professional advice towards the development of our products, whether in a meeting format (e.g., Advisory Boards), or individually, to be carried out under the direction and management of a medical or scientific representative.

1.2.1.1. Company-Sponsored Research (includes post-marketing research)

Almirall does not enter into any research agreements with investigators or institutions with an intent to influence the use or purchase of our products. Any research-related activities carried out by the Company are conducted under the jurisdiction of its clinical or medical departments.

Almirall is committed to avoid any potential or perceived conflict of interest that may negatively impact on the outcomes of any study or the reporting of study results.

Financial compensation to investigators and their institutions or other clinical study personnel shall not:

- Be tied to the outcome of research;
- Consist of company stock or stock options for any portion of the compensation;
- Include compensation to any parties, including HCPs, who are not participating in the study; and
- Consist of incentives or rewards beyond what is prospectively identified in the study agreement and/or otherwise approved by an IRB.

1.2.1.2. Investigator Sponsored Research (ISRs)

Almirall US considers funding or supporting independent research (e.g., research grants, where applicable provision of free study product) only in response to an unsolicited request for support of an independently run study. The principles outlining the Company standards to ensure the ethical and lawful conduct of any IST-related activities are outlined in a Company policy dedicated to this topic.

1.2.1.3. Publications

Research outcomes are published in an effort to share scientific information within the medical and scientific community and, often, in order to satisfy transparency reporting requirements. A publication is any original work intended to publicly disclose medical, scientific, or technical information. Publications may be in the form of manuscripts, abstracts, posters, scientific congress slide presentations, editorials, letters to the editor, review articles, brochures, and other similar

materials intended for dissemination, regardless of the media used (e.g., oral electronic, paper or other media). Almirall is committed to high standards of medical and scientific integrity, transparency in presenting research results and communicating information about its research programs, development candidates, and marketed products in an accurate, objective and balanced fashion. Our communications are undertaken responsibly and aligned with existing laws, publication guidelines, applicable regulations and scientific journal and congress requirements.

Copyrighted information from any source, where used in a Company publication, must have the specific, documented approval from the publisher and/or the information owner. The right to use or disseminate already published information shall be governed by copyright laws and the Company agreements with the owner and/or publisher of the information.

The International Committee of Medical Journal Editors (ICMJE) has issued The Uniform Requirements for Manuscripts Submitted to Biomedical Journals (“Uniform Requirements”), intended to provide criteria and standards which contribute to the improvement of the quality of medical science reporting. The ICMJE criteria have become the golden standard for journal publications. We are committed to abide by the principles stipulated in the ICMJE Uniform Requirements, as well as the Good Publications Practice guidelines adopted by the International Society for Medical Publication Professionals (ISMPP).

Key ICMJE criteria refer to the requirements to be met by authors and the standards for ethical interactions between HCP authors and the industry, including as they refer to the responsibilities to disclose and report those relationships, any exchange or transfer of value between manufacturers and external authors, and any role played by a third party vendor or writing agency towards the publication.

Publications must accurately reflect the opinions and conclusions of their authors. To that end, and in keeping with the ICMJE criteria, authors of Almirall US sponsored publications must:

- Have made substantial contributions to the conception and design of the research, the acquisition of data, or its analysis and interpretation; and
- Have participated in drafting the publication, and/or revising it critically for important intellectual content; and
- Have given final approval of the version to be published; and
- Agree to be accountable for all aspects of the publication, ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

If, through the course of developing or finalizing a Scientific Publication, an author’s contribution changes such that he or she does not continue to meet the authorship criteria noted above (e.g. would not approve the final version of the publication), he/she will be removed from the authorship

line and listed in the acknowledgments section. While we do not pay honoraria to any author solely for their contributions to writing a publication, at times, we may consider offering authors professional assistance (e.g., medical writers) to facilitate the development, writing, or formatting of publications or to facilitate communication among the authors. Regardless of the use of professional assistance, all publication activities must follow professional ethical guidelines and practices.

To the extent that Almirall US offers professional assistance to Scientific Publication authors, the Company will pay Fair Market Value rates for bona fide services by third party providers (e.g., statistical services, medical writing services) that are exclusively limited to the development of the publication itself. In all cases, authors are required to disclose any and all financial support and relationships with Almirall and others who would potentially influence their work as described in publication (e.g., a third party vendor). Any sponsorship, assistance or services provided by the Company to any author must be disclosed in the publications, including Almirall's role in the underlying research, if any, as well as any transfers of value towards the benefit of the author, as required by applicable transparency laws (e.g. Open Payments).

While we may in certain specific instances, provide financial support towards the development of a review article or journal supplement, it is Company policy not to author this type of publications unless they are safety-driven or directed to support public health. Almirall US does not author or provide financial support to case reports or series.

1.2.1.4. Communications with Compendia and Other Drug Information Sources

Compendia are respected sources of information about the use of medicine in clinical practice, and payers increasingly refer to them as a valuable source for making coverage decisions. Most recognized Compendia in the United States are: American Medical Association Drug Evaluations (AMA-DE), United States Pharmacopoeia-Drug Information (USP-DI) or its successor publication and American Hospital Formulary Service-Drug Information (AHFS-DI)

Where applicable (e.g. upon approval of a new drug or, as necessary, to update or revise medical information), Almirall Clinical and Medical Affairs representatives may submit to recognized Compendia relevant, non-promotional, balanced, objective, scientifically sound, and factual information, which do not present any interpretation or conclusions regarding the safety or efficacy of a Company-marketed product. Our communications with Compendia must be transparent and conducted only by members of the scientific departments. Under the umbrella of scientific communications, these submissions are data driven and they never include any claims, or otherwise endorse or recommend an unapproved use of a drug or compound. Some Compendia may require a processing fee for submissions. Almirall US will make only those payments necessary to comply with the submission requirements as outlined and documented by the respective Compendium and **will not** offer or provide any other form of financial support. Any payments made to Compendia must be approved by Medical Affairs or the Company Chief Compliance Officer.

Documentation of all the submissions, communications and payments to Compendia must be retained according to the company record retention standards.

1.2.1.5. Formulary and Payer Interactions

In order to evaluate the benefits, costs and other consequences of competing therapies, particularly in managed care formulary settings, managed care experts may need access to Healthcare Economic Information (HCEI) about FDA-approved uses of Company products. Almirall US designates authorized staff members or company representatives (e.g. Managed Markets, Medical Affairs) acting on its behalf to provide information or interact with formulary, Pharmacy & Therapeutic (P&T) committees or other payers. Such authorized personnel must be properly trained, and must limit the scope of information exchange about product reimbursement to: a) identification of relevant reimbursement coverage; and b) company-approved coding or billing information and/or procedures.

HCEI may include: a) treatment guidelines; b) health outcomes data; c) pharmacoeconomic or population-based outcomes; and d) other analyses that identify, measure, or compare the economic costs of health outcomes with the use of one drug versus another, with the use of one drug versus a different intervention, or versus no intervention at all. According to regulatory requirements (e.g., Food and Drug Administration Modernization Act, Section 114), HCEI:

- May only be shared with representatives of a formulary committee or similar entity that is responsible for evaluating the benefits, costs and other consequences of competing therapies. HCEI must not be shared with individual HCPs, who may be making treatment decisions for individual patients, and who are not designated by such committee or entity to act on its behalf;
- Must be:
 - Supported by competent and reliable scientific evidence;
 - Directly related to an approved labeled indication;
 - Reviewed and approved by PRC for this purpose

Materials containing HCEI, which have been approved by PRC for this purpose, cannot be used for advertising and/or promotional activities.

As a result of an unsolicited request for information from a P&T or Formulary Committee, the Company may provide through its Medical representatives, information about clinical data and related study results, only if done in compliance with applicable FDA guidance and delivered to adequately qualified committee representatives.

1.2.1.6. Advisory and Consulting Engagements

Almirall recognizes that treatment options and patient needs are constantly evolving. In order to have a good understanding of the current treatment patterns and build on our internal expertise, we sometimes have to rely on the real-world knowledge and clinical understanding of medical practitioners. As necessary, we have to engage health care professionals to work with us as professional advisors or consultants, providing insight, expertise and advice on a range of topics, such as:

- Real time knowledge and understanding of treatment options in a certain therapeutic area or disease state, and how they differentiate from our medicines;
- Assessment of research opportunities for a disease state or an Almirall US marketed product;
- Expert opinion when conducting business development-related activities or other market research assessments.

In order to accomplish these needs, and maintain compliant with current laws, regulations and industry codes of practice that govern industry relationships with the medical community, each HCP engagement must be reviewed and approved by the Almirall US Medical Affairs and Compliance. A HCP Engagement Proposal must document:

- Legitimate scientific or business rationale for the engagement;
- Number of advisors or consultants to be engaged;
- Selection criteria required to meet the business need;
- The name and qualifications of selected candidates, as applicable, and how they meet the selection criteria;
- Type (e.g., hourly, daily/meeting) and length of engagement (e.g. hourly for 6 months; two-day meeting) and if there is a compensation cap.
- A description of how the advice received will be documented and used by the company;
- Fair market value compensation for the engagement;
- Identification/description of any venue, meals and other transfers of value, as applicable.

a. Advisory Boards

Advisory Boards are company-sponsored, non-promotional meetings triggered by Almirall's legitimate business need to engage one or more HCPs as consultants for any of the areas outlined above. Almirall's policy prohibits organizing Advisory Boards with an intent to promote our products, share unapproved product information or to reward, induce, or attempt to influence in any way HCP prescribing decisions or practices.

The number and frequency of Advisory Boards held annually by the Company must correlate to a documented, *bona fide* need. The number of healthcare experts that are invited to participate in a Company-sponsored meeting must be limited to what allows for valuable exchange and the opportunity for each participant to provide meaningful input.

Field sales personnel are not permitted to select, or approve invitees to participate in an Advisory Board meeting, cannot execute contracts with HCPs, attend these type of meetings or otherwise be involved in their planning and operation.

Venues reserved for these events cannot be lavish. Advisory Boards must be held in a non-resort location that is conducive to a business meeting and the exchange of information, without potential distractions from the meeting's objective. Modest meals, including beverages, and snacks may be provided as consistent with the company policy regarding applicable limits and section 1.1.5 of this Code. Entertainment and recreational activities are not permitted in conjunction with any HCP engagement, including Advisory Board meetings.

Invitations to attend the meeting, as well as all the materials disseminated or presented by Almirall in conjunction with the meeting must be approved by the appropriate review committee, with representation from Medical, Regulatory Affairs and Compliance. Materials typically include:

- A detailed agenda of the meeting, including the time allotted for presentations and discussions. The Agenda must reflect the fact that the event is planned and designed to seek information, and thus, the time allotted to the advisors' feed-back must significantly outweigh the time during which Company representatives present information (e.g. balance between push versus pull of information);
- Advisory Board materials and slide presentations, including pre- and post-meeting work materials for advisors.

In addition, for this type of meetings, the following details are reviewed by the Compliance office:

- A summary of the overall objective(s) of the advisory board meeting.
- The number of advisors that will be engaged for the meeting, noting whether any invited advisor will serve as the program moderator or chair.
- Company representatives attending the meeting, who in general should have a role in presenting information or moderating/facilitating the discussions (this includes any third party vendors). The number of company representatives in attendance should be always less than the number of advisors invited, with a consideration of a maximum 1:2 ratio wherever possible.

b. Consulting engagements

Expert professional advice may be obtained within the framework of a formal meeting, as well as on an individual basis, such as an individual consulting arrangement. Often, a single advisor or consultant may be sufficient to offer the information sought. Examples may be situations where there is a safety-related question, or need for periodic consultation on a specific project, where an expert practitioner may have to be engaged for a longer period of time to provide opinion at several stages during that project. Other times, Company representatives may consider engaging several experts on an individual contract basis, where each of the consultants provides their individual, personal opinion and the Company assesses those individual opinions in order to make its own decision on how to proceed in a specific situation (for example, in a business development or other type of market research-related activity). For any HCP consulting arrangement, the function responsible for the engagement must outline HCP selection criteria that address the legitimate business need prior to considering any individual HCP for such engagement.

All the other criteria and requirements outlined in this Code regarding the engagement of HCPs for any fee-for-service arrangement apply to consulting engagements, regardless of the format in which the advice is obtained, bearing in mind that for individual engagements outside of a meeting the meeting-related requirements may not apply.

1.2.2. Promotional Interactions & Information Sharing

Informing health care providers about our medicines while directing them to their approved indications and key safety information is one way in which our representatives interact with the medical community and educate its members about their appropriate use. These interactions equally enable us to learn about the HCP's firsthand, practical experiences with our drugs, thus helping us consider ways in which we can enhance our contributions to improving health outcomes and patient lives.

Any promotional communication that we engage in, however brief or informal, is limited to on-label, FDA-approved information, is complete, truthful, accurate, it contains a fair balance between the benefits and risks of a product, and is approved by the Promotional Review Committee (PRC) through the internal Almirall US promotional review process. We accompany our detail and other product communications with the applicable approved product label and/or package insert.

Our sales representatives and any other Company representative who engages in promotional activities must use the most current approved promotional materials and related product labeling during any interactions with HCPs and other customers. The risks associated with our products cannot be overlooked or minimized. Almirall does not allow statements that compare the efficacy or safety of one product to another, known as “comparative claims,” unless such claims are supported by head-to-head clinical trials which were designed to detect different outcomes in similar patient populations by applying comparable dosing regimens of those products. Sales representatives may not make comparative claims regarding competitive products unless the PRC approved materials refer to, or include such permissible statement or claim, when based on one or more head-to-head clinical trials.

1.2.2.1. Call plans

All promotional communications carried by our Company representatives are directed to HCPs who prescribe or treat patients within FDA-approved indications and patient populations for that product. We strictly prohibit the targeting or detailing of HCPs who do not treat patients within the FDA-approved patient population for any of our products.

Call Plans are developed by responsible Almirall US functions reporting outside of the Sales organization, are approved by company management and are managed with the support of third party vendor(s). These Call Plans document and inform which prescribers may be called on and detailed regarding a specific product, disease state, or therapeutic area, based on the approved indication(s) and patient population in that product’s label.

1.2.2.2. Promotional messages & materials. Reprints

As outlined above, all content used in conjunction with the promotion of a Company product must be approved by PRC. PRC is the committee responsible to verify and confirm that the content used to promote a product is medically accurate and consistent with the FDA-approved label for the indication, patient population, dosage, route of administration, etc. The composition of PRC is cross-functional, with representation from Medical, Regulatory Affairs, Marketing and Compliance.

In addition to content review of the material, PRC also reviews and approves any graphics and messages associated with promotional campaigns/activities, as well as intended audiences. Some materials that require PRC review are:

- Sales training materials, including visual aids, sales aids, and “slim jims” in hard copy, electronic, or mobile formats;
- Scientific journal articles in the form of “Reprints”, which may be used in promotion;
- Slide decks and presentations (i) used in promotion, including during promotional Speaker Programs, and (ii) non-promotional content to be used during Advisory Board meetings (Ad Board material review is conducted with participation from Medical, Regulatory Affairs and Compliance);

- Materials to be used and/or presented during professional conferences or congresses;
- Web sites and any digital communications sponsored or supported by the Company;
- Patient educational materials, including unbranded disease awareness and disease education materials;
- Any other materials or communications that include a promotional claim about the efficacy or safety of a Company product.

Almirall US developed a detailed standard process outlining the requirements for PRC submission, review and approval of materials.

At times, copies of journal published articles may be used either in support promotional claims, or to facilitate scientific exchange during non-promotional interactions (e.g. Consulting). Only Reprints that meet the criteria outlined in most current regulatory guidance may be approved for use by PRC. Depending on the content of the Reprint and the purpose of the activity, Almirall US will share only company-approved, unabridged publications, published in peer reviewed medical and scientific journals, which present accurate, balanced scientific information that is current, relevant, and objective. Where approved by PRC and used in promotion, Reprints shared with HCPs by Company representatives may not be discussed, interpreted, or argued as far as the author’s conclusions, Equally, they must not be associated with or appended to any promotional message or material. In general, our Company’s approach to information-sharing by use of Reprints is to communicate, or disseminate such information through its qualified representatives and under the oversight of our home office management, without the direct participation of any sales representatives regardless of their position in the company. All copyright responsibilities and obligations must be met prior to any use of Reprints and the actual value of any Reprint provided to an HCPs (and not the cost of that Reprint to the Company), must be reported as a transfer of value, consistent with the requirements of the Affordable Care Act – Open Payments.

To the extent that any promotional materials are used by any Company representative, those must be used **only as approved** internally by PRC, without being abridged, altered, edited, marked, flagged, highlighted, or presented with any other method of emphasis or de-emphasis..

1.2.2.3. Addressing unsolicited requests for off-label information

Unsolicited requests for off-label information may be addressed only by members of the Company scientific department or its designated representative(s). Representatives of the Almirall US commercial organization, including any members of the sales organization, **are not permitted to engage in any discussions that include a reference to an off-label indication of a company product**. Should an unsolicited inquiry for off-label information be raised in their presence, they have a duty to inform the requestor that the requested information is not included in the product label (i.e., is “off-label”), reiterating the product’s FDA approved indications, and advising that he/she is not authorized to address the question(s). The HCP may be directed to the Company Medical Affairs representative, by providing the appropriate contact information, or assisting with the completion of the Medical Inquiry Request Form (MIRF), subsequently to be submitted for response to the Almirall US Medical Information designated center. Sales representatives may not call the Medical Information line and/or ask questions on behalf of HCPs or other customers. Any MIRF submitted as a result of an unsolicited inquiry must include the authorizing signature of the requesting HCP.

1.2.2.4. Sample Distribution

The Prescription Drug Marketing Act of 1987 (PDMA) prohibits the sale, purchase or trade of drug samples. It is illegal for a physician to sell, or seek reimbursement for a free sample. Individuals who engage in or encourage such conduct are subject to criminal prosecution. Drug samples could be considered “remuneration” under the Anti-kickback statute if given to an HCP for the wrong reasons, such as offering a personal benefit to the HCP, or with an intent to induce them to prescribe, purchase or recommend the use or purchase of an Almirall product.

Some states have specific laws that specify whether samples may be provided and to whom they may be dispensed. For example, some states have particular limitations on distributing certain samples and some impose specific reporting timelines for samples that were lost or stolen. These laws are continuously evolving and it is our responsibility to maintain current at all times with the requirements for our individual area(s) of responsibility. Moreover, states have various approaches to which HCPs (e.g., nurse practitioners, physician assistants) may prescribe drugs and as such, who might be authorized to accept samples.

For sampling programs approved by the company, Almirall abides by the key principles that our (i) sampling program meets the requirements of the Prescription Drug Marketing Act of 1987 (PDMA) and the company’s policy on sampling, and that (ii) free samples shall only be distributed to physicians and other prescribers who are authorized under state law to receive and dispense samples.

It is a policy violation to distribute samples to:

- Retail pharmacies;
- Wholesalers, even when they are designated as custodian of such samples by a HCP;
- Lay persons or other healthcare providers who are not licensed practitioners;
- Any practitioners while attending conventions, displays or symposia.

Complete documentation of any sampling transaction, including the requesting practitioner’s signature, full sample accountability and sample loss, transfer, expiration or disposition must be maintained in compliance with company standards and processes.

1.2.2.5. Expert-Led Promotional Meetings

a. Speaker Programs

Company-sponsored Speaker Programs are planned and conducted to foster education of the medical community about our products, therapeutic areas, or disease states of interest, in the interest of advancing and protecting patient health and quality of life.

Almirall sponsored Speaker Program content is grounded in science and is governed by our commitment to accurate, complete, fair and balanced scientific information. All speakers are informed and educated about the laws and regulations that apply to industry-sponsored communications about medicines to ensure that any information discussed about our products is consistent with applicable regulatory agency requirements, including the applicable industry codes of practice (e.g. PhRMA Code). Speaker presentations are PRC reviewed/approved and keep consistent with FDA-approved product labeling and fairly balance the benefit and risk

information about our products.

Speakers selected by the Company to present during our Speaker Programs must be:

- licensed and in good standing with the Department of Health & Human Services Office of Inspector General, the Food & Drug Administration and the governing regulatory agency in their state of practice.
- compensated according to fair market value (FMV) guidelines defined according to their specific qualifications and the amount of time necessary to provide the requested service
- reimbursed for out-of-pocket expenses as appropriate and as defined in the speaker's agreement. Almirall may cover travel or food expenses incurred by the speaker in connection with speaking engagements, when valid documentation of approved expenses is produced.

Only those speakers who are properly qualified, meet the selection criteria and have an executed current Speaker Agreement are allowed to participate in the pool for speaker selection. The authorized qualified Speaker is the only participant in the program who may be paid for the services provided during a Speaker Program presentation. Other health care professionals who are in attendance may not be paid or otherwise compensated for attendance, however they may participate in modest meals offered in conjunction with the event.

Under no circumstance shall Promotional Speaker Programs be planned or conducted, nor any speakers be engaged with an intent to induce or reward the prescription, purchase or referral of a Company product. Any materials used towards presentations during an Almirall-sponsored promotional Speaker Program must be approved in advance by PRC, and must comply with applicable regulatory requirements. Approved materials may not be edited, revised, condensed, flagged, and/or presented with added or diminished emphasis.

b. Speaker Training

HCPs engaged to present during Company-sponsored Speaker Programs receive appropriate training from the responsible Almirall US functions on how to conduct the program, including:

- pertinent compliance requirements, and
- instructions about the product or disease state to be presented, based on PRC approved materials

HCPs may be offered reimbursement for reasonable travel, lodging, and meal expenses.

Speaker Training Meetings are conducted in venues that are appropriate and conducive to the business activity.

1.2.3. Rules of engagement between sales and medical

During the course of conducting regular business activities, sales representatives and members of the Medical Affairs organizations, have opportunities to interact with each other, as well as with external customers, including HCPs. Almirall ensures that these interactions occur in the most professional, ethical and compliant manner, in order to eliminate any potential perception of inappropriate influence or conflict of interest between the two functions, or between the Company and its customers.

In all cases, during interactions with HCPs, our representatives' demeanor must keep consistent with the Company Code of Conduct, its policies and standards and this Code of Interactions with Healthcare Professionals.

a. External Interactions

In a Healthcare Professional Office:

External interactions between Medical Affairs representatives and sales representatives may occur in certain situations when both may conduct business in the same territory at the same time. These functions however fulfill different roles and work independently of each other.

Joint calls on HCPs that involve both sales representatives and Medical Affairs staff are not permitted, except when introduction to a HCP occurs at an initial meeting. In these circumstances, the different roles of the Medical Affairs and the sales representative are explained to the customer, as applicable, and each representative individually attends to their business objective during separately allocated time frames.

During Scientific or Medical Meetings & Conferences:

Almirall participates in scientific or medical conventions and conferences that are relevant for its business. At such meetings, the Company may receive inquiries that include unsolicited requests for information regarding an Almirall product. Such responses must be provided only as outlined in this Code and the applicable Company policies.

When staffing a conference booth, sales representatives must operate within the dedicated Almirall commercial booth, where promotional exchanges are planned to occur. Any discussions and/or exchange of information taking place in this booth and in general, any conversations and exchange of information conducted by sales representatives must be restricted to approved, on-label information and PRC-approved content regarding any Company product or disease state.

Medical Affairs staff are only permitted to operate in an area dedicated to Medical (e.g., Medical Information booth) and refrain from engaging in scientific exchange that involves Off-Label information about an Almirall product outside of the booth, and especially in the presence of a sales representative or commercial colleague. The Medical booth must be sufficiently separated /distinguished from the promotional booth.

Prior to or following a speaking engagement, Medical Affairs staff, whenever present, may assist with providing scientific support to individual HCPs who are engaged as Speakers at an Almirall sponsored event,.

Upon invitation or an inquiry from a Formulary Committee (including from a Formulary Committee member when acting on behalf of the Committee), may make presentations of approved material, that contains a fair balance of data, consistent with the requirements of applicable laws and this Code about communication and dissemination of Healthcare Economic Information (HCEI). Neither comparative analysis of safety or efficacy parameters, nor any conclusions about safety or efficacy are permitted during such presentations. Where Off-Label information about an unapproved product is requested by a Formulary Committee, the information may be included in a presentation, provided that the information is explicitly tailored to address the Unsolicited Request and has been reviewed and approved via the applicable internal review process.

b. Internal Interactions

Communications between medical and scientific department representatives and representatives from commercial departments must be limited to on-label topics. Cross-functional meetings may be held with management representatives from medical and commercial functions to the extent to which such

meetings and discussions are geared towards planning or developing company or marketing/product strategies. Tactics regarding the achievement or implementation of any approved strategic plans must be developed and approved by the responsible department. For example, any scientific and non-promotional activities, such as research studies, whether interventional or non-interventional, publications, medical education, and certain advisory board meetings must be planned and approved under the supervision and oversight of the medical function, while marketing plans, speaker programs or call plans, shall be developed and approved under the supervision of commercial departments.

Scientific or medical function representatives are often involved with training the sales force or HCP Speakers engaged by Almirall US, by using PRC-approved materials.

In situations when, upon receipt of an unsolicited request from a customer, a sales representative may need to engage one or more members of the scientific or medical department to participate in a scientific exchange, they must submit a request to the Medical Information department documenting such need, in accordance with the established Medical Information Request process. A sales representative must never attempt to obtain a response to an off-label question on behalf of a HCP, regardless of whether they attempt to contact an internal medical department employee or the third party Medical Information call center. Equally, a medical or scientific function representative must never provide an off-label response to a sales representative regardless of the circumstances under which the inquiry was received. The only permissible interaction in such circumstances between a sales and a medical functional representative is to share on-label, or logistics information, such as the customer's location, schedule, etc.

1.2.4. Compensation & Other Transfers of Value

1.2.4.1. Fee for service

Almirall compensates HCPs for services provided to the company with reasonable fees, based on the FMV applicable to the nature and length of their engagement and the individual HCP's qualifications and expertise. All the payments made by the Company are consistent with the stipulations agreed upon in the written contractual agreement with the HCP, including as they apply to any out-of-pocket reimbursements and payee information. We do not issue payments to HCPs unless it has been documented and verified that the work product has been received according to contractual obligations, and that the payment is issued to the HCP's payee of record, and not to anyone else, including any third parties towards the benefit of the HCP, such as a charity or similar entity.

1.2.4.2. Business meals

In conjunction with an informational product presentation, the exchange of scientific and medical information, or business discussions, occasional and modest business meals may be provided to HCPs and, as applicable, members of their staff. Meals provided by Almirall are incidental to the business or clinical discussion and are provided only in the context of a legitimate informational exchange.

In general, with the exception of promotional Speaker Programs, field sales representatives and their direct managers may provide a meal or refreshment to HCPs and their staff only when the meal occurs in-office or in a hospital setting.

However, during national medical conventions where Almirall has a commercial presence (i.e., exhibit booth), field sales employees or their direct managers may attend a meal hosted and arranged by company management (e.g., Marketing). Field sales employees and their managers must not participate in the planning or arrangement of any aspect of the meal, or be involved with any payment arrangement towards the meal or any portion of it.

Out-of-office meals may be provided to HCPs only by specifically authorized Company representatives at the Director level or above, where they are scheduled in the context of an informational exchange.

All meals must comply with the following criteria:

- The meal must be modest in nature;
- The venue must be conducive and appropriate for the business discussion;
- At least one Company employee must be present for the duration of the meal (i.e., “dine and dash” meals are prohibited);
- The meal must be occasional in nature with respect to the same individual(s);
- Guests of an HCP, or any of their family members (e.g. spouses), including non-HCP participants who would not customarily have a professional interest in the discussion, may not be invited or permitted to participate in the meal;
- Applicable state laws and any relevant institutional limitations must be followed and complied with.

For U.S. healthcare professionals, meal upper limits applicable to any Almirall sponsored meals, inclusive of food, beverage, tax and gratuity, are:

In-office meals:

- Breakfast: US \$25 Per Person
- Lunch: US \$25 per person

Out-of-office meals (Director level or above participation only):

- Breakfast: US \$ 25 per person
- Lunch: US \$ 50 per person
- Dinner: US \$150 per person

For major metro areas (e.g. New York, Los Angeles), where conference or professional meeting venues cannot meet the standard policy rates outlined above and there is not an opportunity to negotiate such rates (e.g. one-on-one lunch appointment), a maximum allowance of US \$35 for breakfast and US \$75 for lunch is permissible, when Headquarters personnel at a Director level or above have a legitimate business need to discuss professional topics over breakfast or lunch.

All participants in a meal, including Almirall participants, are included in the total number of participants when calculating the per person cost for any meal.

Special Restrictions

State Laws and Standards: Certain U.S. state laws, regulations, guidance or standards may be more restrictive than this Code and expressly provide limitations upon the ability to offer meals, gifts and other items of value to HCPs. Almirall makes every effort to comply with all applicable laws and regulations when operating in those territories, or interacting with HCPs who practice in those territories. Always understand the state laws and apply the more conservative standard when that differs from the stipulations of this Code.

Institutional Restrictions: Academic and healthcare institutions may have special rules that apply to the actions of pharmaceutical representatives who visit their facilities or interact with their employees, including HCPs. These restrictions may include limitations on the provision of meals and educational items. Almirall staff and representatives have a responsibility to make themselves familiar and maintain

compliance with all institutional requirements that are relevant to their professional interactions.

1.2.4.3. Gifts and Entertainment

Almirall may occasionally provide an educational item to a healthcare professional, in order to advance the education of either the HCP or their patient(s). Any such items must be unsolicited, internally pre-approved by the PRC and made available or provided by the Company for distribution. Examples of acceptable educational items may be:

- Anatomical model for use in an examination room
- Medical textbooks
- Copies of relevant clinical treatment guidelines
- Informational sheets and brochures

Items that are personal in nature, or which are intended for the personal benefit of a practitioner, their employees and/or family, regardless of value, are prohibited. Unless further restricted by an applicable state law, regulation, or institutional policy, the value of any educational item considered by Almirall for distribution may not exceed US \$100, as determined according to the item's fair market value and not its actual cost to Almirall. The provision of cash or cash equivalents (e.g. credit or gift cards), is strictly prohibited. Some examples of items that **cannot** be provided to healthcare professionals are:

- Product branded items of any kind
- Tickets to entertainment events (e.g. sporting events, theater, concert, etc.)
- Clothing items, (e.g. hats, or caps)
- Sports equipment (e.g. golf balls) or fitness items (e.g. pedometers, stopwatches)
- Personal electronic, or computer devices (e.g. DVDs, MP3 players, or similar)
- Wine or any other alcoholic beverages
- Gift baskets, candies, flowers,

Almirall does not provide any form of entertainment or recreational activity to HCPs and discourages the participation of our employees or representatives in entertainment activities with healthcare professionals, regardless of who is paying for the activity.

1.2.5. Independent Medical Education

Almirall supports the advancement of knowledge and to that end may consider providing educational grants in support of *bona fide* meetings, seminars, conferences, and other programs that are designed to communicate healthcare information with the noble purpose of educating the medical community and promoting legitimate scientific exchange. Educational grants considered for an award by Almirall are in general for programs that are conducted by institutions, professional organizations, or accredited independent medical education (IME) providers (e.g., Accreditation Council for Continuing Medical Education (ACCME), Accreditation Council for Pharmacy Education (ACPE), American Nurses Credentialing Center (ANCC), state medical societies).

In order to receive consideration for an award, IME grant requests have to meet all of the following criteria:

- designed to support independent educational programs and activities that relate to therapies, disease states, or other public health subjects in therapeutic areas in which we participate through our products or research;
- non-promotional in nature
- developed and conducted by an independent third party without any influence or control from Almirall.

We do not provide financial support or educational grants to individual physicians, private practice groups, health plans, or managed care organizations, regardless of their tax status. The sponsoring education provider is solely responsible for the selection of content, faculty, educational methods, materials, and venue for the program. Almirall does not interfere or provide input to independent educational programs on either their content or faculty selection, even when such assistance or input might be requested by the provider.

Grant award funds may be used by the education provider as it deems fit, including towards compensating program faculty according to the provider's policies and practices, or paying for the cost of modest meals for the program participants. However, Almirall educational grant funds may not be used directly or indirectly to compensate an attendee to facilitate his/her attendance at the program. Sales and marketing employees, or any of the Company's third party representatives, cannot proactively suggest, solicit or discuss grant requests during their interactions with physicians, institutions, or other professional organizations.

Almirall-sponsored promotional activities may not be conducted on location where a Company-supported educational program is taking place. Advertising for Almirall or its products cannot be included in or added to any educational program materials. Our representatives, when they happen to attend an Almirall-funded educational program, cannot promote or otherwise discuss our products with any of the attendees, or attempt to supply them with food, drinks, gifts or any type of favors.

1.2.6. Sponsorships and Charitable Contributions

Almirall may support certain third-party independent, scientific and educational conferences or professional meetings, provided that the conference or meeting content:

- a) contributes to the improvement of patient care or the enhanced delivery of healthcare; and/or
- b) promotes or advances scientific and medical knowledge.

Requests for event sponsorship may be submitted to Almirall commercial representatives, who in collaboration with Medical & Compliance must follow the principles of this Code and all other pertinent laws and regulations to review the requests and make decisions about the company's participation in any sponsorship opportunity.

Where approved, sponsorship funding is paid directly to the conference organizer or training institution, and is never made to third parties or payees who are not identified and approved in the formal request for funding. As a result Almirall may benefit from opportunities to display corporate signage or other approved materials, as stipulated in the pertinent documentation of approval. At the event, either the meeting organizer and/or Almirall discloses to participants the company's scope of sponsorship for any part of the activity.

Charitable organizations seeking funds from our Company must submit a written request that includes the following:

- Letter describing the requesting organization,
- Proposed event or activities,
- Amount of contribution requested;
- Evidence that the organization is a *bona fide* non-profit, tax exempt 501(c)(3) charitable organization in good standing;
- Written confirmation of tax-exempt status (W-9 or IRS letter);
- Written representation that the organization is in good standing and its activities are in full compliance with all relevant laws, regulations and OIG guidance documents.

Charitable contributions are only approved when they support *bona fide* charitable purposes. Any past, present or potential future purchase or use of Company products has no bearing on the committee's decisions. Any awarded charitable fund contributions are unrestricted and may be used at the sole discretion of the recipient.

1.2.7. International Markets - Anti-Bribery Anti-Corruption (ABAC)

Almirall US and its business partners may conduct business activities outside of the U.S., or interact with business partners who are citizens of foreign countries. In all cases, we must conduct ourselves in a manner that is consistent with the provisions of the anti-bribery and anti-corruption laws applicable to our business [e.g., Foreign Corrupt Practices Act (FCPA)]. We recognize international and local laws, and where the local laws are more stringent than the Company policy requirements, we apply the more stringent standard.

Almirall condemns and prohibits any form of corrupt payments. A corrupt payment is represented by cash or a payment in kind (i.e. use of a good or service as payment instead of cash) promised, offered or given in order to assist the company in obtaining or retaining business, or to secure preferential treatment (i.e., an improper business advantage). The business to be obtained or retained does not need to be with a foreign government or governmental entity.

To that end, any third party provider who is engaged to perform an activity on behalf of the Company in a territory outside of the U.S. must undergo a selection process that includes confirmation of a legitimate business need for the engagement, a background review that is appropriate for the type of engagement, and adequate oversight of the activities it performs. HCPs engaged by state-owned institutions are considered by our standards to meet the definition of a government official and will be treated as such.

In situations when Almirall is considering the acquisition of a new asset, adequate due diligence is conducted and the acquired entity is assessed according to these principles.

It is a violation of this Code to offer or make any corrupt payments, directly or indirectly (i.e., through a business partner), while knowing that all or even a portion of the payment will be given to anyone, whether a government official, a business, or a private individual, in order to gain an improper advantage.

Employees or agents of the Company who encounter a situation where they observe or suspect that a corrupt payment is made, offered, demanded or extorted, must promptly report the situation to their management, the Almirall US Compliance Officer, or via the Company dedicated Hotline.

1.3. Transparency

1.3.1. Disclosures

In the spirit of transparency and in order to meet the applicable laws, requirements and industry codes of practice, Almirall is committed to comply with its obligations regarding disclosure of the nature of its interactions with HCPs and healthcare institutions. Whether engaging in scientific activities, such as clinical trials or publication of scientific developments, sponsoring educational activities or industry events, awarding grants or charitable contributions to legitimate entities, or engaging and compensating HCPs towards the advancement of our business, we will always be transparent and open about our interactions to the extent required by laws, regulations, industry codes of practice and this Code.

1.3.2. Reporting

1.3.2.1. Adverse Events (AE)

Almirall continually monitors the quality and safety of all of our products, including after they are marketed. Timely reporting of safety information is not only a legal obligation, but also a reflection of our commitment to patient safety.

An Adverse Event (AE) is any untoward medical occurrence, in a subject or patient administered a medicinal product, whether the medical occurrence is, or is not, related to the administration of such medicinal product. This may be an unfavorable or unintended sign, symptom, disease, or change in an existing condition, which occurs in conjunction with the administration of a drug or biologic in humans, regardless of whether it is considered to be related to that drug or treatment, or not. AEs may also be called “adverse drug experiences,” “adverse drug reactions,” or “side effects.” In addition, events that represent a lack of effect of a marketed product, or which result in improper dosing, abuse, or drug withdrawal are considered AEs.

Should you become aware of an actual or potential AE and other reportable safety information relative to one of Almirall’s products, whether through interactions with a healthcare professional, a distributor, a patient, or any other customer, you are responsible to report it within 24 hours of becoming aware of it by contacting the Almirall US Contract Medical Affairs Provider (CMAP) via Email at: almirallmc@dlls.com or by phone at: 1-866-665-2782.

We are committed to collect, analyze and timely report to the FDA, complete, accurate and meaningful safety information about our products. In addition, in the spirit of transparency and our responsibility to science, patient safety and the medical community, when we learn about new or updated information about the safety profile of our products, we communicate timely and keep HCPs informed, in compliance with the applicable regulatory requirements and our professional responsibilities.

1.3.2.2. Open Payments

We are required by law to capture and report on an annual basis, information about payments made to HCPs or teaching hospitals as a result of our professional engagements and collaborations. Public posting of this information is made on a government hosted website as required by the Affordable Care Act, Open Payments stipulations. Upon publication, physicians & teaching hospitals have an opportunity to review information being reported about them and dispute any perceived discrepancies.

To meet these obligations, we must accurately capture all transfers of value to HCPs, including consulting payments, meals, scientific journal reprints and other items of value, in a timely and accurate manner. These laws, are intended to provide the public with insight into interactions between the pharmaceutical industry and HCPs, deter misconduct and build the public trust regarding the nature and legitimacy of these professional collaborations.

Employees and business partners who interact with HCPs and teaching hospital on our behalf must provide timely and complete details regarding payments, benefits, reimbursements, other compensation, educational and other items of value, meals, or hospitality that are provided to HCPs in accordance with this Code and company policy.

As state laws may vary in the level of restrictions relative to the transfer of value to an HCP, those who conduct their professional activity in states that have transparency laws, are responsible for understanding the requirements that apply to their business activities and comply with the local law standards and the requirements of this Code, by applying the most conservative approach.

Attachment A – Frequently Asked Questions (FAQ)

Q: One of the HCPs that I am detailing in my territory is very interested in our acne products, and often tells me how he likes to use one of them for an indication that is not FDA approved, and therefore not listed in the product label. I have some background information from our internal research, which I might share with him to clarify his understanding, or answer his question. Should I do that in the interest of time?

A: Always remember: any discussion or information that you share or discuss with external customers or business partners is deemed promotion. Do not attempt to discuss or promote the use of any Almirall product for any parameter that is not approved in its labels. Your option is to direct this HCP to the Almirall Medical Affairs call center, whose staff is trained, qualified and has the adequate processes and systems to address these types of questions.

Q: I am a sales manager detailing a new physician assistant (PA) prescriber in my territory. We just met each other and had a pleasant conversation. As I am getting ready to wrap up my presentation about our new topical gel, it occurs to me that it might not be a bad idea to ask the PA to join me for dinner and drinks later in the day. After all, it never hurts to build good relationships with a new customer who might help with my quota, especially when it won't cost me a penny because I can expense this cost as part of my monthly allowance. My supervisor will not ask questions, nor would we have to report the expense on public websites, as the client is not a physician. Is it OK to go ahead and offer the meal? What should I do?

A: In your role, as a sales manager, you are not allowed to participate in meals with HCP customers outside of the office setting unless the meal occurs in conjunction with a Company-approved Speaker Program. Taking a prescriber out for a meal without prior company approval represents a violation of the Company policy, and may be perceived as an attempt to influence prescribing decisions by offering an inducement or payment-in-kind.

Q: Is it appropriate to bring lunch for the medical office staff to whom I will be presenting educational information about our product?

A: Yes. It is appropriate to offer a modest meal in conjunction with an informational or educational presentation made to medical office staff during lunch hours.

Q: I am a sales manager and am hosting a Speaker Program later this week. The Speaker is asking for a car service, as it is inconvenient for her to take public transportation. The car service should not be that expensive. Should I go ahead and book it?

A: Personal car service for a Speaker, or any other customer, is not appropriate unless it has been previously approved in writing by the Company senior management and Compliance, on a case by case basis. For example, if public or commercial transportation does not exist from the Speakers' location to the location of the program venue, it might be appropriate to allow for this service if the Speaker may not otherwise be able to get to that venue. However, the review and written approval from Compliance is required in advance for each individual instance, in order to avoid the perception of undue favors to a HCP in a potential quid pro quo scenario (i.e., incentivizing or rewarding an HCP for his/her prescribing practices).

Q: I have been provided with a PRC approved product presentation to use when introducing our new product to my customers. I think that in some sections I would gain some advantage by customizing the deck and slightly

revising the approved materials. I could even highlight the sections that could emphasize what I want my customers to focus on. Isn't this a good idea?

A: No. Our educational and promotional materials are developed through a rigorous review and approval process, which ensures that they meet the applicable regulatory and legal requirements for promotion in our industry. It is never permissible to use materials which have not been previously approved internally by the Company PRC, or modify in any way (e.g. highlight, emphasize, deemphasize) any approved materials, including visual aids.

Q: We are having a hard time introducing local physicians to one of our recently approved products. One of my colleagues recommended that we conduct a study and enroll local physicians as investigators in order get them acquainted with our product and enhance our efforts to introduce it. Is this ok?

A: No. Studies must have scientific merit, may only be conducted to serve a scientific, research purpose and should **never** be intended to “seed” the market or promote a product. Paying healthcare professionals to conduct “sham studies” is considered a kick-back.

Q: My top prescriber is raising money for her son's soccer team, so that they can attend an out of state tournament. Since she supported our Company by writing a lot of prescriptions for our products, I think that Almirall should support her and her son in return.

A: Using money, money equivalents, or other things of value to incentivize or reward a prescriber for recommending or purchasing a healthcare product is against the law and the principles of our Code. Medical decisions should be made independently, free of influence, and based on a healthcare professional's best judgement regarding quality patient care. Paying in order to incentivize or reward a prescriber for their prescribing practices represents a corrupt act, which we as a Company do not tolerate.

Q: While travelling for business, a fellow traveler mentioned that one of our products which she recently used, gave her an itching rash. She could have used it incorrectly because the next time she used the same product it stopped giving her the redness, and according to her, it really helped with her acne. Do I have to report this conversation? In my opinion this could not be a related adverse event.

A: Yes, you must report any adverse event that you become aware of and which is reported to have occurred in conjunction with the use of an Almirall product. Although it may not appear that our product caused this event, those who are qualified and responsible for such determinations, in this case the Almirall US Medical Affairs representatives, should be notified.



Attachment B – Employee Acknowledgement and Certification Form

Employee Acknowledgment and Certification Form

Almirall, LLC

Code for Interactions with Healthcare Professionals (HCP)

I received a copy of the Aqua Code for Interactions with Healthcare Professionals (HCP), dated October 2018.

I certify that I will read, understand and abide by this Code, including the standards and requirements that are referenced therein.

I understand that any violation of this Code may result in corrective and/or disciplinary action up to, and including termination of my employment with Almirall.

Almirall reserves the right to modify this Code at any time in its sole discretion.

Signature

Date

Print Name

Title