

**Kimberly-Clark Healthcare
Guidelines for Dissemination of Medical and
Product Information**

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Introduction to Guidelines for Dissemination of Medical and Product Information

Kimberly-Clark Healthcare (“K-C”) is committed to compliance with the U.S. healthcare laws and regulations that govern the sale and marketing of its products. In addition, K-C is committed to ensuring the highest integrity and accuracy of all data, claims, and general communications disseminated to external stakeholders, such as healthcare professionals, patients, caregivers, payors, and regulators. Compliance demonstrates our commitment to integrity in our operations and builds trust with patients, healthcare professionals, institutions and the government. These guidelines are an application of the K-C Corporate Code of Conduct. These provisions provide greater guidance with respect to certain laws that uniquely affect the K-C Healthcare business.

These guidelines are meant to establish a uniform way of disseminating labeling and promotional materials, which are disseminated for the purpose of marketing our products. These guidelines should serve as instructions for the categories of materials that are covered. If you have any questions or are unsure how to interpret or apply these guidelines, please seek guidance from your team leader, or you may contact the Legal Department.

Overview of the Laws and Standards

In general, the Food and Drug Administration distinguishes between scientific exchange of information, intended to provide objective, factual data to educate a healthcare professional, and product promotion, intended to highlight the benefits of a particular product to encourage its sale. Scientific exchange of information may include: disease state communications (that do not identify a particular product), recruitment of investigators or subjects for a clinical trial, and Continuing Medical Education meetings. Scientific exchange may also include responses to unsolicited requests for information.

FDA recognizes that certain information about, and access to, current research and scientific data can be educational and non-promotional. Accordingly, manufacturers may participate in the full exchange of scientific information concerning their products, including dissemination of scientific findings in medical or lay media, so long as the information is truthful, objective, and complete. However, if K-C disseminates such materials that mention a K-C product, FDA may regulate the piece as labeling and hold the company responsible for regulatory compliance with its promotional requirements.

Federal Food, Drug, and Cosmetic Act

The key federal law in the United States that governs the development of labeling or promotional materials for the marketing and sale of medical devices is the Federal Food, Drug, and Cosmetic Act (“FDCA”). (There are other laws, including the False Claims Act and the Federal Anti-Kickback Statute, as well as industry and professional standards, which apply to K-C’s interactions with healthcare professionals. These laws and standards, and how they relate to

K-C's business operations, are described in K-C's Guidelines for Interactions with Healthcare Professionals.)

Under the FDCA, all labeling, advertising and promotional materials disseminated by or on behalf of a manufacturer must:

1. contain certain mandatory information, such as product name, name of manufacturer, and contents;
2. not be false or misleading; and
3. must present a fair balance between a product's risks and benefits.

For pre-approval discussions, where FDA has not approved or cleared the product, K-C may not commercialize, promote, represent, or suggest that the product is safe, effective or approved in the United States.

FDA regulates label and labeling, whether or not it is intended for commercial, promotional, or educational use, if it mentions or describes a K-C product.

FDA interprets broadly the definitions of "label" and "labeling," which are written, printed, or graphic material on, accompanying, or describing the product. Labeling includes information on the product label, the prescription information or instructions for use and other descriptive materials provided by K-C about its products. Any materials used to promote K-C products, including all media advertising, brochures, detail ads, promotional programs and third-party information must be consistent with the approved/cleared product labeling.

FDA does not typically regulate the following as labeling: disease state communications, CME-related materials not distributed by the manufacturer, and verbal statements, but such activities must nevertheless be truthful, objective, and otherwise not provide information about unapproved, off-label uses of K-C products.

With very limited exception, FDA considers any materials issued by, or on behalf of K-C, or any events sponsored by K-C that mentions or describes one or more products (explicitly or implicitly) to be regulated labeling or promotional activity. Therefore, all K-C materials intended for external dissemination, whether written or oral communications, must comply with applicable laws, rules, and regulations and must proceed through internal review.

How to Use These Guidelines

These guidelines apply to K-C materials used to market our products in the United States. Although our use of marketing material in other areas of the world are technically not covered by these guidelines, we will abide by these guidelines globally. Thus, these guidelines apply to all K-C Healthcare personnel who distribute medical or product information.

Implementation and Enforcement of These Guidelines

Compliance with these guidelines is mandatory. A violation of these guidelines subjects you to discipline in accordance with our existing disciplinary policies. Depending on the number of infractions or the nature of the offense, penalties may include an official reprimand that will be included in the individual's personnel file, job reassignment or demotion, or employment termination. The Vice President of Sales and Marketing, the Vice President of Regulatory Affairs, or the Medical Director as appropriate, will consult with the Legal Department in evaluating the conduct and the disciplinary actions to be taken, if any. Additionally, a violation of these guidelines may subject you to sanctions under federal law. In appropriate circumstances, K-C may report such cases to law enforcement authorities.

If you learn of conduct by an individual employed by K-C, or working on K-C's behalf, who does not comply with these guidelines, or if you believe you might have inadvertently failed to comply or are unsure, you must report the conduct. These reports should go to your team leader, the Compliance Officer, or the Legal Department. If you would like to make your report anonymously, you may make the report to K-C's Ethics Hotline. All reports should be made in good faith based on a reasonable belief that misconduct has occurred. No K-C employee should be concerned about any reprisal or reprimand for coming forward with a report; K-C encourages open and proactive communication and dialogue.

The responsibility for implementing these guidelines will lie with the K-C Legal Department. K-C will provide regular training to employees including, but not limited to, sales and marketing personnel, to ensure compliance with applicable laws and company guidelines. In addition, K-C will conduct audits, at least once a year, to monitor compliance with the K-C guidelines and will investigate, when appropriate, potential instances of non-compliance.

The Legal Department will be charged with enforcing these guidelines, and any modifications to or deviations from these guidelines must be approved by the Legal Department.

Tab A

Promotional Materials – General Policy

1. K-C products are to be promoted on the basis of their efficacy, safety, therapeutic value and benefit to patients.
2. Materials issued by or on behalf of K-C that mention one or more K-C products are considered to be labeling and/or promotional materials.
3. All promotional materials must be approved via the K-C review process prior to external dissemination. Under no circumstances are field sales personnel allowed to create, alter, or modify approved promotional materials, i.e., no homemade materials.
4. Field sales personnel may order approved promotional materials via the materials ordering system. These items have been approved via the K-C review process for a specific use in promoting K-C products. They may not be used in a different setting without additional K-C review. For example, a physician detail piece may not be distributed to consumers unless it was approved for that purpose.
5. Training materials are considered to be confidential and are not to be used in promotion to customers. These materials are for background educational information purposes only and will be marked as such.
6. Standard medical letters, prepared by Medical Sciences, Regulatory Affairs and Legal, are designed to respond to unsolicited and unprompted information requests from customers about approved and unapproved uses of K-C products, and they are not to be used in promotion.

Tab B

Prohibited Proactive Promotion of Unapproved Uses

FDA approves or clears a product for use only as described in the label and approved or cleared package insert or instructions for use to treat specific diseases or specific patient populations. Any other use is considered “unapproved” or otherwise referred to as “off label.” In clinical practice, healthcare providers may sometimes prescribe or recommend products for unapproved uses in the exercise of their professional standards. However, K-C employees may not solicit, encourage, or promote unapproved uses of a product.

K-C is permitted to provide truthful and non-misleading scientific information about unapproved products or unapproved uses in certain limited circumstances and within certain prescribed cases. For example, K-C may provide information, as long as the information is communicated to the healthcare professional in a truthful and balanced manner by a member of K-C’s Medical Sciences Department, in compliance with FDA requirements. See Tab C.

Any proactive dissemination of off-label information by a K-C Medical Sciences individual, even if not promotional in nature, requires review by K-C’s Medical Review Committee (“MRC”).

K-C Guidelines

K-C employees and anyone retained to speak on behalf of K-C cannot proactively offer off-label information in a promotional manner, nor can they solicit questions about unapproved uses. As a general rule, when an unsolicited off-label question is posed to K-C medical personnel, a brief and medically accurate response is provided. Requests for information about potential unapproved uses of our products must be directed to the K-C Medical Sciences Department or otherwise handled only in a manner and with information, such as reprints, that have been approved by the Medical Sciences Department or the MRC.

Field Representatives, in response to unsolicited requests for information regarding an unapproved product or off-label information regarding an approved/cleared product, shall act in accordance with the following:

1. For an unapproved product, the Field Representative shall state that the product is still in clinical development and cannot be discussed any further. No K-C representative shall recommend the unapproved product be used as medical treatment.
2. For approved products, the Field Representative should not attempt to promote the product for any such unapproved use and should not volunteer or suggest additional information, except within labeling.

In either event (situation 1 or 2 above), the Field Representative shall refer the inquiry.

Field Representatives shall refer the inquiry to K-C's Medical Sciences Department. The Field Representative may give the healthcare professional the contact number for K-C's Medical Sciences Department at the time of inquiry. The Field Representative may also provide any material previously approved by the Medical Sciences Department or MRC, in the manner approved by the Medical Sciences Department or MRC, if the material is directly responsive to the unsolicited request.

The Field Representative shall document the request and forward to the Medical Sciences Department. The documentation shall include the Field Representative's name, the name and address of the healthcare professional, a written description of the nature of the request, the date of the request, and a list of any material given to the healthcare professional.

Medical Sciences, upon receiving an unsolicited request for information, shall act in accordance with the following:

1. Medical Sciences should only respond using material (including Peer-Reviewed Reprints) that have been approved by K-C's Green Folder Process and Yellow Folder Process. K-C's Medical Sciences Department shall tailor its response to the specific question or request. Any information provided should be complete, accurate, and balanced. K-C should not offer any editorial commentary on, or opinion about, the materials. See Tab D.
2. The response must include a balance of relevant information, meaning not merely that which is favorable to K-C. If any materials are provided in response to the unsolicited request, the Medical Sciences Department, in consultation with Regulatory Affairs, should include the approved or cleared package labeling and a disclaimer that:
 - a. K-C is responding to a specific request;
 - b. the product is approved or cleared only for a specific use, with the approved or cleared labeling attached;
 - c. there may be information that discusses other potential uses, not approved or cleared by FDA; and
 - d. the materials are for educational purposes only.
3. Any and all responses to an unsolicited request for information should be documented. The documentation should include the following:
 - a. the date of the inquiry;
 - b. the form of the inquiry (by phone or in writing);
 - c. the name and address of the healthcare professional;
 - d. a description of the request; and
 - e. the nature and form of the response to the request, including a record of any materials sent to the healthcare provider, and documentation that any such material has been reviewed and approved by K-C's Medical Review Committee.

The Medical Sciences Department shall retain copies of the documentation.

Tab C

Scientific Exchange of Information

Even though FDA typically does not consider legitimate scientific exchange of information to be product promotion, non-promotional scientific exchange of information is subject to all the rules and regulations that govern the communication of K-C's products, meaning it must be a truthful, on-label, and consistent with the FDA-cleared labeling. Scientific exchange does not allow K-C to disseminate unapproved information that is potentially false, misleading or poorly substantiated. In addition, K-C personnel are not allowed to encourage investigators or other physicians to communicate unapproved information. K-C personnel may not suggest an investigational new product or unapproved indication for use is safe, effective, or approved.

The following sections will delineate several types of activities that may constitute "bona fide scientific exchange," including scientific presentations and exhibits at conventions and meetings, distribution of medical reprints, and "medical-to-medical" communications and the K-C guidelines that regulate their use. In addition, this section will discuss which personnel may engage in scientific exchange in different contexts, as well as the consequences of improper scientific exchange.

Scientific Presentations and Exhibits at Conventions and Meetings

Scientific presentations may be classified as legitimate educational exchange if all of the following criteria are met:

- The speaker is a scientist or clinician;
- The information is of important, current scientific interest and not widely known in the medical community;
- The presentation is accurate and scientifically balanced as to its claims;
- Safety issues are fairly presented and not minimized;
- Uses outside of approved labeling are not emphasized and are disclosed;
- The legend "Please see full prescribing information," "Instructions for Use," or similar verbiage is prominently displayed;
- The content is developed by, or in collaboration with, an investigator who is independent of K-C;
- K-C's role in the research and presentation is clearly disclosed; and
- The presentation is segregated from promotional activities and beyond the perimeter of the promotional booth.

Medical-to-Medical Communication

The objective of the K-C Medical Sciences Department is to provide accurate, timely and scientifically fair and balanced medical information to health care professionals. Communications between K-C medical personnel and health care professionals are considered to be a "medical-to-medical" type of communication, enabling K-C to appropriately respond to

unsolicited inquiries that may require reference to both on-label and unapproved uses and to assist in patient and investigator recruitment for clinical trials.

“Medical-to-medical” communication is defined as one scientist or physician engaged in non-promotional discussion about a subject outside of a product’s approved labeling with other physicians or scientists. “Medical-to-medical” communication that involves K-C medical personnel shall be conducted on a limited basis and in venues as determined by the K-C Medical Review Committee (MRC). Such “medical-to-medical” communication must be non-promotional, unsolicited and scientific exchange.

K-C Medical Sciences personnel who receive an unsolicited request for information that goes beyond the scope of approved labeling may provide a brief and/or verbal response to the question but clarify the regulatory status of the product. The answer should not go beyond the scope of the question. If K-C Medical Sciences personnel disseminate any written material, the procedures and conditions described in Tab B must be followed.

K-C Medical Science Liaisons (MSLs) are considered to be members of the Medical Sciences department and are instrumental in conducting communications with K-C sponsored clinicians and Key Opinion Leaders (KOLs). They are also instrumental in assembling medical advisory panels and coordinating the sponsorship of CME programs within the context of various venues. As members of K-C’s Medical Sciences departments, K-C’s MSLs can engage in “medical-to-medical” communications with Medical Directors, Directors of Pharmacy, physicians and other professionals about K-C’s products. MSLs can also respond to field-based inquiries about the availability of clinical and educational resources (e.g., educational programs, investigational grants). They may also address unsolicited questions pertaining to the unapproved uses of K-C’s products but may not initiate such discussions or engage in such discussions in a promotional context. In all cases when engaging in “medical-to-medical” communications, the MSLs must do so in an objective and balanced manner and make clear the product’s regulatory status.

Tab D

Non-Promotional Reprint Distribution

Periodically, K-C may wish to disseminate information that describes a potential use that is not approved. The purpose of such dissemination is to educate the healthcare professional about disease states or new treatments but not to actively promote the product for an off-label use or in a false or misleading manner. K-C's MRC will review and approve which material may be distributed.

In order to be considered for dissemination, the information must be described in a scientific article that has been peer-reviewed and published by an organization of national scope that has an editorial board. The material in the article should be based on adequate and well-controlled studies and cannot be false or misleading.

The MRC shall use the following rules when evaluating the dissemination of non-promotional information:

- The information cannot be false or misleading about treatment or product use. It also cannot be an "outlier" when evaluated in the context of a broad array of scientific evidence. This type of selective dissemination is not allowed.
- The proposed distribution format must draw the reader's attention to any significant differences from the approved labeling (such as effectiveness rates, data, analysis, uses and regimens) and to the product's regulatory status. This may be done by attaching a cover sheet.
- The dissemination of, and discussions pertaining to, MRC-approved information may only be conducted in accordance to the direction provided by the MRC. In addition, all questions about unapproved information or questions about the content should be directed to the Medical Sciences department and the procedures and conditions described in Tab B must be followed.
- The MRC will decide how to respond, disseminate and document such information.

A reprint does not include letters to the editor, posters, abstracts, reports of Phase I clinical trials, or any reference publication that does not contain a substantive discussion of relevant investigation or data. These materials may only be disseminated after MRC review and in response to an unsolicited request for information.

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K-C's guidelines permits limited distribution of third-party, peer-reviewed scientific and truthful information from medical journals or textbooks about potential product uses that are not

approved in defined circumstances and only after review and approval by the MRC. In no event should the material suggest the potential use is safe, effective, or approved.

K-C Field Representatives may distribute peer-reviewed reprints or other scientific information from medical journals or medical textbooks that has been approved by the MRC, through the Green or Yellow Folder Process, in accordance with the following:

1. The Field Representative shall distribute the approved reprint with the product's approved or cleared package labeling and a disclaimer that: (a) the product is approved or cleared only for a specific use in accordance with the attached approved or cleared labeling; (b) the information may discuss other potential uses, not approved or cleared by FDA; and (c) the materials are for educational purposes only.
2. The Field Representative shall distribute only materials reviewed and approved by the MRC. Homemade pieces are prohibited.
3. The Field Representative shall not make any marks, highlight any information, or in any way characterize or summarize the approved peer-reviewed reprint. The approved reprint shall be distributed separately from other promotional material regarding the product. However, any promotional materials except a peer-reviewed journal article or medical textbook as described above shall not contain off-label information.
4. In no event shall the Field Representative engage in a discussion about the reprint or any off-label use and should refer questions per the procedures and conditions described in Tab B.

Tab E

Auditing

K-C shall monitor compliance with these guidelines through the following auditing procedure. On a yearly basis, or more often if warranted, K-C shall conduct an audit to determine compliance with these guidelines. The audit shall consist of collecting and analyzing documentation related to the dissemination of off-label information. The audit shall group the documentation, at a minimum, by the following categories: (1) product; (2) the therapeutic area covered by the dissemination; (3) the name of any Field Representative involved; (4) the name of the healthcare professional; (5) relevant dates (e.g., the date of an unsolicited request and date of dissemination of information); and (6) the method and forum of dissemination, such as, for example, in response to an unsolicited request, a proactive dissemination of an approved reprint, or material given out during a scientific conference.

K-C shall analyze the audit reports to determine whether there is any indication of the dissemination of off-label information or information regarding an unapproved product not in accordance with these guidelines. Any indications of violations shall be promptly investigated and documented in accordance with K-C's policies and procedures for handling of investigations. If a violation is found, corrective action shall be taken and documented.

In addition to the annual audits described above, K-C shall conduct observations of the dissemination of information at scientific or medical conferences to ensure compliance with these guidelines and, on occasion, join Field Representatives on sales calls and attend promotional activities.

The Auditing program described here shall be consistent with K-C's general auditing program requirements and procedures.