



Collegium Code of Marketing Practices

I. Overview

At Collegium Pharmaceutical (Collegium), we take the promotion of our products very seriously. It is our ethical responsibility to provide accurate, balanced and updated information about our products to healthcare professionals, patients and consumers. These fundamental principles guide our marketing practices and interactions with healthcare professionals and customers:

- Product promotion must accurately reflect the benefits and risks of a medicine.
- Any information we provide must consider the needs of our customers and must be consistent with the FDA-approved product labeling.
- Sponsorships of medical or scientific events must be clearly disclosed, and the event's purpose must have at its core, the sharing of relevant medical or scientific information.
- Hospitality must be appropriate, modest, consistent with local business practices and secondary to the main purpose of providing relevant medical or scientific information.
- We do not provide gifts or entertainment of any kind to healthcare professionals or their families.
- We prohibit any personal incentives for the recommendation, prescribing, use, or favorable formulary or medical guideline position of our products.
- Samples (if provided) are for patient trial usage and for the enhancement of patient care and in a manner that complies with PDMA regulations.
- All marketing interactions and activities comply with all applicable federal and state laws and regulations, guidances and Collegium policies.
- As a responsible pharmaceutical marketing company Collegium supports the FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics.

II. Introduction

Interactions with and collaboration between healthcare professionals and Collegium is central to improving the quality of care for patients and to conducting the necessary research to deliver unique and improved treatments for patients. It is through interaction and collaboration on research for new medicines or developing new and improved delivery systems for existing products that patient care is enhanced.

At Collegium, collaborating with healthcare professionals outside our company on research for new medicines, new delivery systems or learning about treatment options leads to innovative thinking, better treatments and medicines for patients. In order to maintain the highest level of integrity and responsibility in these interactions, Collegium has established this Marketing Code of Conduct.



III. Key Principles

A. Independence of Healthcare Professionals

Nothing may be offered or provided to a healthcare professional intended to have an inappropriate influence on the healthcare professional's decision to recommend, prescribe, dispense, purchase, or place in a favorable formulary or clinical guidelines position, Collegium products.

B. Interactions with Healthcare Professionals

The ultimate purpose of all interactions with HCPs is to enhance patient care and/or the practice of medicine.

As a responsible pharmaceutical marketing company, Collegium supports the FDA *Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics* and supports their April 2011 Risk Evaluation and Mitigation Strategy (REMS) to ensure that the benefits of extended-release and long-acting (ER/LA) opioid analgesics outweigh the risks. The REMS supports national efforts to address the prescription drug abuse epidemic. It includes education for prescribers of these medications, which will be provided through accredited continuing education (CE) activities supported by independent educational grants from ER/LA opioid analgesic companies. It also includes information that prescribers can use when counseling patients about the risks and benefits of ER/LA opioid analgesic use.

C. Separation between Promotion and Non-Promotion

Activities and interactions whose objective is to promote approved Collegium products is openly considered promotional, may not be disguised, and must follow the FDA guidelines on product promotion. Activities and interactions that are conducted to foster scientific exchange or non-promotional medical education must be free from sales and marketing influence and be structured and managed accordingly.

Activities and interactions conducted with the purpose of receiving information and advice or to obtaining important scientific input or data, such as advisory boards and post-marketing studies, may not have the promotion of products as any part of their purpose. Such activities may only be used as a means to gather information for Collegium to develop compounds and market FDA-approved products. Non-promotional activities, such as advisory boards, market research, clinical studies, etc., must have as their genuine objective to obtain needed, scientifically relevant and unbiased information and may not be designed in any way to achieve promotional objectives. Care must be taken to ensure that not even one purpose of an activity may be interpreted as promotion or the entire activity might be considered promotional.

D. Promotional Content

All promotional content produced/disseminated by Collegium (in printed/electronic form and communicated orally) must be accurate, scientifically sound, objective, reflect the current state of knowledge and be consistent with the FDA-approved prescribing information. Additionally, Collegium and its representatives must provide a fair balance of product benefits and risks including adverse events and contraindications when promoting our products.

E. No Pre-approval or Off-label Promotion

Collegium does not promote a compound or product in the U.S. until approved by the FDA.



Promotion and advertising of a compound prior to regulatory approval is prohibited. However, this provision is not intended to limit the right of the scientific community to be fully informed on important scientific and medical progress. It is also not intended to restrict full and proper exchange of scientific information concerning a compound or product including appropriate dissemination of investigational findings in scientific communications and at scientific, non-promotional events. It is also not intended to restrict public disclosure of information to investors/shareholders concerning products in accordance with law or regulation.

Information on unapproved compounds/products and indications in the form of reprints from scientific and medical journal articles, may be given to healthcare professionals by the Medical Information department upon receipt of an unsolicited healthcare professional's request. The response, including any reprints provided by the medical department, must be accurate, not misleading and not promotional in nature. It must relate solely to the subject matter of the inquiry and must be properly documented and retained as required by Collegium policy. Furthermore, Collegium sales representatives must never be involved in disseminating off-label information as part of a product discussion. They may, on occasion deliver scientific reprints to healthcare professionals consistent with the FDA's February, 2014 *Guidance for Industry: Distributing Scientific and Medical Publications on Unapproved New Uses – Recommended Practices*.

While it is legitimate and useful to inform healthcare professionals on scientific/medical progress at medical congresses and conferences, care must be taken to ensure full transparency with regard to approved indications and unapproved uses. Trademarks, brand logo, brand colors and tag lines must not be associated with any unapproved indications in order to clearly separate promotion from non-promotion.

The risk of unintended pre-approval/off-label promotion is especially high at international events, due to possible differences in product registrations/approval status. Compassionate use programs, extended access programs and clinical trials do not constitute promotional activities and must comply with all applicable laws, regulations and codes relevant for human research studies. Care should be taken to ensure that communications relating to such programs are not, in effect, advertisements for an unapproved compound or an unapproved use of an approved product.

F. Adverse Events Reporting

All Collegium employees, vendors and contractors are required to report actual or suspected Adverse Events and Drug Experiences within 24-hours of becoming aware of the adverse event by calling Collegium's pharmacovigilance contractor, ProPharma at (1) 855-331-5615.

G. Privacy of Personal Information

Collegium must safeguard all confidential personal information in its possession against misuse or inappropriate disclosure and avoid any unauthorized access in accordance with applicable laws and Collegium policy. Personal information may only be collected for a clearly defined legal justification which may include a business purpose and only with the explicit consent of the individual. Furthermore, the information collected may only be used for the purpose defined in the consent, be limited in its access to only those individuals that a valid business reason to use it, and be anonymized whenever feasible. Finally, the information may only be retained for as long as necessary for the intended purpose.



H. Educational Events

The purpose and focus of all educational symposia, congresses and other scientific or professional meetings for healthcare professionals organized or sponsored Collegium must be to provide relevant scientific or educational information and/or inform healthcare professionals about products in therapeutic areas in which we focus.

Collegium may fund educational symposia, congresses and other scientific or professional meetings for healthcare professionals to attend providing:

- The funding does not interfere with the independent decision making of healthcare professionals involved;
- The funding is limited to travel, meals, accommodation and registration fees for those involved in presentation of the educational content;
- Healthcare professionals attending the programs are not compensated for time spent at the events;
- Collegium does not pay for any costs associated with guests or other persons accompanying HCPs;
- No private funds are used by Collegium employees to engage in activities that are not allowed by our Code of Conduct, this Code of Marketing Practices or Collegium policies.

I. Promotional Information at Educational Events

Information that appears as part of a promotional exhibit booth or that is distributed to participants at scientific congresses and symposia held in the U.S. must comply with all FDA promotional regulations.

J. Dissemination of Scientific Information

Scientific information consistent with a product's FDA-approved label may be disseminated by Medical Affairs employees at a Medical Information booth or at a specific Medical section of a conference exhibit booth. When Medical Affairs employees share a space within an exhibit booth, no commercial employees are permitted within that area. Medical Information employees may respond to unsolicited requests for off-label information providing no commercial employees are present and such requests are documented consistent with Collegium policies.

K. Appropriate Venue

All events must be held in an appropriate venue that is conducive to the scientific or educational objectives and the purpose of the event or meeting. Collegium may not use renowned or extravagant venues or venues associated with recreation or entertainment.

L. Hospitality and Entertainment

When Collegium organizes a meeting, refreshments and/or meals incidental to the main purpose of providing relevant medical or scientific information at the event may be provided. Refreshments and/or meals may only be provided: (1) exclusively to healthcare professionals at the event; and (2) if they are moderate and reasonable as judged by local business standards. As a general rule, the value of hospitality should not exceed what the HCPs would be prepared to pay for personal purposes.



No entertainment or other leisure or social activities may be provided or paid for by Collegium. It is not permitted to fund the attendance, purchase tickets or pay for entertainment in any form. However, if there is background music or a local performance at the event where the meal is taking place, which is not paid for by Collegium, this is permitted. Any other entertainment, even if secondary to the meal is prohibited.

M. Speakers

The purpose of engaging HCPs to speak at events is to share relevant scientific/educational information. Accordingly engaged HCPs must be experts in a given field. The engagement must be based on a written contract containing a clear description of tasks and responsibilities. Fees and expenses must be reasonable and fair market value in relation to the services rendered. The engagement of HCPs as speakers must not interfere with their independent decision making relative to the treatment of patients.

Collegium selects speakers based on their expertise in the specific therapeutic or disease area and their ability to communicate information to their colleagues in a clear and engaging manner. Collegium never engages HCPs as Speakers based on their recommendation, past, present or future use, favorable formulary or clinical guideline position of any Collegium product.

N. Grants

Grants may only be given to patient, professional or healthcare-related organizations, and never to individuals. All such organizations must be vetted to ensure they are legitimate, reputable, and not involved in any potential improper activity. Such vetting may include prior experience with the funding recipient or publicly available information such as organizational documents (e.g., bylaws, annual reports, etc.), the organization's website, or recent media coverage.

All grants must be request through appropriate channels, properly documented (including a signed agreement) and never involve Sales or Marketing in the grant decision-making process. Grants are not promotional activities and no return on investment analysis may be conducted.

Educational grants are intended to support independent educational activities (accredited or non-accredited) where the grant recipient is responsible for content development and for managing the educational event. Collegium may not control the content of the program or the faculty, and the grant recipient controls the selection and invitation of any healthcare professionals.

O. Other Funding Arrangements

Many daily business activities are managed under other funding arrangements. In other funding arrangements, Collegium receives a tangible benefit in exchange for funding provided to healthcare-related institutions, and the arrangement is defined in appropriate supporting documentation (i.e., a contract for services). The tangible benefit must not constitute any form of inappropriate inducement. Other funding arrangements may be for a commercial or non-commercial purpose, and must always follow Collegium's customer contracting processes.

P. Donations & Charitable Contributions

Collegium may make donations or charitable contributions to reputable healthcare or healthcare-related institutions for an altruistic, non-business related purposes, and where Collegium does not receive or will not be perceived to receive a direct or indirect consideration or service in return. The overall purpose of a donation or



charitable contribution is to support activities/projects with an affinity to our mission in the fields of healthcare and medicine or to support various initiatives, projects or non-profit organizations in the local community in which Collegium operates and which are in line with our commitment to Corporate Citizenship.

Q. Additional Standards for Interactions with Healthcare Professionals Who Are Public Officials

Healthcare professionals working at public hospitals or government institutions may be defined as ‘public officials’ by anti-corruption laws. In order to ensure strict compliance with national and international anticorruption laws, such as the US Foreign Corrupt Practices Act (FCPA) and the OECD Anti- Bribery Convention, interactions with public officials must comply with the following additional requirements (please note that an increasing number of countries have changed/are changing their laws to extend the applicability of these anticorruption requirements to interactions with private persons):

- All benefits conveyed to public officials must be fully transparent, properly documented and accounted for; and
- Collegium requires written assurance from the relevant public hospitals/government institutions, that benefits conveyed (e.g. funding attendance to events or engaging public officials as experts/speakers) do not violate applicable local laws and regulations.
- If obtaining that written assurance is unduly complicated, the invited Public Official shall confirm in writing that the collaboration is consistent with his or her professional duties.
- Appropriate documentation may include an invitation and agenda.