Brief Guidelines for marketing Code

GIFTS, ITEMS OF MEDICAL UTILITY, DONATIONS AND GRANTS

1 General Principles

No gift/rewards, incentives, donations, financial, and the like shall be offered or given to healthcare professionals in return for prescriptions or recommendations for a company's medicine(s) or product(s).

1.1 Gifts

1.1.1 Gifts in Cash or cash equivalents (Vouchers, etc) shall not be offered to any HCP and shall not exceed Thai Baht 3,000 (Thailand) or USD 100 (Overseas)

1.1.2 The gift must not fall under the circumstances/ possible consideration of Bribery which can be resulted if he or she provides a benefit to another person; causes a benefit to be provided to another person; offers to provide or promises to provide a benefit to another person when the benefit/ return is not legitimately due to that person and the person offering the benefit does so with the intention of influencing a Government official & Medical Professionals in order to retain or obtain business or a business advantage.

1.1.3 Customary gifts may be provided on an infrequent basis such as New Year, anniversary, funeral, etc.

1.1.4 The gifts shall be provided as per the procedure and limits as laid down below.

1.1.5 Inappropriate/ Irrelevant items as gifts:

A. Non-Medical device electronic items: DVDs, CD players, Mobile Phones including credit top-up cards, Computer Equipment, etc.
B. Pre-paid Vouchers
C. Alcoholic Beverages, Cigarettes & Drugs (both legal & illegal drugs/ substances by Local Law)

Purpose: This procedure shall detail the steps to be taken by the employee/ managers/ Directors/ 3rd Party representing mega for Gifts and Hospitality being extended to any Government Official/ HCP.

Procedure: All proposed gifts and hospitality extended to the concerned persons shall be within the limits set by Mega. In case the limits set by Mega are higher than the limits set by the 3rd party Principal whose products Mega is marketing then the limits of such partner shall be considered as the limits of Mega for all purposes.

All such gifts or hospitality of an amount greater than the limits shall be approved by the Location's Managing Director and shall be referred to the Compliance team.

No proposed gift or hospitality shall be approved unless it meets the following criteria:

a) Reasonable and customary under the circumstances

b) Should be permitted under local law

c) Should be permitted by transnational laws if applicable.

d) Should be provided openly and recorded in the Books with appropriate narration.

e) Should be at par with professional standards.

f) Should not be in the form of Cash or securities.

The voucher or request form should mention the name of official, number of officials, purpose and the cost per unit and per person for the gifts.

Any Gifts/ Hospitality exceeding the limits shall be placed for approval by the Managing Director/ Compliance team minimum 07 days in advance.

Gifts/ Hospitality can be extended to Government Officials attending a conference/ seminar/ symposium hosted by Mega for a business purpose as per the limits under this policy. The event shall be documented by the organizing department.

Gifts/ Hospitality extended should be requested for payment by accounts should be accompanied with a request form provided below.

Form for requesting payment for gifts to Government Officials/ HCPs.

Name of the Requesting person:

Sr. No.	Name of the Official/ HCP	Title (including the organization name)	Nature of Gift	Value of Gift	Purpose	Date of last gift given.

I certify that the gift is for bona fide purpose and is not in any form a Bribery measure or for obtaining any undue benefits.

……. ……

Requested By Approved By

1.3.2 The total value of such items shall not be more than USD 50 per HCP per time.

1.3.3 Items must not bear the print of product name, but may have MEGA Logo or the Name.

Promotional Aids

Guidelines for Promotional Aids to HCPs

1.1 Promotional Aids are non-monetary aids given for promotional purposes.
1.2 Promotional Aids are given to assist an HCP in its professional performance.
1.3 The Promotional aids can be minimal value and quantity.
1.4 Items for personal use cannot be considered as Promotional Aid.
1.5 Promotional aids shall be considered as brand reminders and shall include the product name but will not include any claims including tag lines and/or statements.
1.6 Value of Promotional Aid shall not exceed USD 20 per item per time.

Items of Medical utility

Guidelines for items of Medical Utility

1.1 Medical utility items might include an anatomical model for use in an examination room or medical textbooks, as both primarily involve a patient benefit.
1.2 Value of such items shall not exceed Thai Baht 3,000 (Thailand) or USD 100 (Overseas) per item per time.
1.3 The medical utility does not offset routine business practices and is beneficial to enhancing the provision of medical services and patient care.
1.4 Medical item will not be offered on more than occasional basis, even if the individual item is appropriate.

Samples

Guidelines for distribution of Samples

1.1 Samples for Rx products shall be given to only doctors who prescribe them and not to other HCPs.
1.2 The objectives of samples shall be to familiarize the HCPs with the look and appearance of the products, providing to inpatients for initiation of therapy or conducting agreed clinical evaluation of the product.

1.3 Samples shall be distributed by Distributors or by Medical representatives and having due regard to the storage & delivery conditions.
1.4 Samples shall not be made available from unattended stands during events.
1.5 The packs shall be marked as “Samples- not for sale” to prevent misuse or sale of such products.

Post Marketing Surveillance studies

Guidelines for post marketing surveillance studies

1.1 Post Marketing Surveillance Studies shall be for the purpose of ensuring rational use.
1.2 Post Marketing Surveillance Studies shall not be used for marketing purposes.
1.3 Any serious hazards/ effects observed during this study should be reported to the Pharmacovigilance team and Medical Director.

Patient organisation

Guidelines for dealing with patient organizations

1.1 All interactions with patient organizations shall be ethical. The independence of patient organizations must be respected.
1.2 When working with patient organizations, companies must ensure that the involvement of the Company and the nature of the involvement is clear from the outset. No company may require that it be the sole funder of the patient organization or any of its major programs.
1.3 Financial support or in-kind contribution to patient organizations must have in place written documentation setting out the nature of the support, including the purpose of any activity and its funding.
1.4 Company may provide financial support for patient organization meetings provided that the primary purpose of the meeting is professional, educational and scientific in nature or otherwise supports the mission of the patient organization. When company holds meetings for patient organizations, companies must ensure that the venue and location is appropriate and conducive to informational communication. In addition, any meals or refreshments provided by a company must be modest as judged by local standards.

Patient education

Guidelines for patient education materials

1.1 Patient education materials must be current, accurate and balanced.
1.2 The educational material should not focus on a particular product, unless the material is intended to be given to the patient by a healthcare professional after the decision to prescribe the product has been made.
1.3 Educational material may include descriptions of the therapeutic category, medical condition and a discussion of the relevant clinical parameters in general.
1.4 The educational material should include the advice 'Please consult your physician' and the contact number and supplier of the material.
1.5 The educational material must include a statement directing the patient to seek further information about the condition/ treatment from his/ her doctor. Such statements must never be designed or made for encouraging the members of public to ask their doctor to prescribe the product.
1.6 The tone of the message must not be presented in a way which unnecessarily causes alarm or misunderstanding in the community.
1.7 On all occasions the information, whether written or communicated by other means, must be presented in a balanced way so as to avoid the risk of raising unfounded hopes of a particular product.

Patient Aids

Guidelines for patient Aids

1.1 Patient aids which are solely intended to provide information for the patient once a decision to prescribe that product has been made, may be product specific. The content of such material must be designed to assist with patient compliance by providing information which clarifies method of administration, precautions and special instructions and like information. It must not make comparisons or include promotional claims.

Patient support programs

Guidelines for patient support programs

1.1 Company may participate in patient support programs/ activities provided these activities are not done with the intention to market prescription products to patients.
1.2 Any payment for the work undertaken by Healthcare professional is commensurate with the work undertaken.
1.3 No incentives, other than material that will enhance positive health outcomes and compliance are provided to patients to become involved in this program
1.4 The program complies with applicable laws.
1.5 All information provided to patients must comply with requirements under Patient Aids and Patient Education.
1.6 The data collected from these programs will not be used for any purpose other than to increase positive health outcomes and never for any promotional activities.
1.7 The duration of these programs is appropriate to the disease state treated by the product involved.

Promotion to non-healthcare professionals

Safeguards against promotion of prescription products to non-healthcare professionals

Prescription products cannot be promoted to general public unless such activities are permitted by law. Information provide must be accurate and current. The Company shall adhere to the highest ethical and professional standards in responding to inquiries, creating disease awareness, providing educational messages, etc.

1.1 Request from the members of General public for information or advice on the company product, diagnosis of disease, choice of therapy or personal medical matters should be refused and the inquirer must be directed to consult their doctor.
1.2 A prescription product related media release is not allowed by the FDA; however, it is acceptable to respond to media inquiries. The information provided should be correct, accurate and balanced. Information about the medicine must not encourage members of the general public to ask their medical professional to prescribe a particular pharmaceutical product.

1.3 Company may supply information about a product to lay press only where this is in the public interest or where the objective is to communicate scientific or technical achievement. Such information should be presented in a balanced way to avoid the risk of raising unfounded hopes.
1.4 General Media Articles concerning specific prescription products must not be initiated. However, information on medical conditions is allowed.
1.5 Company should not attempt to encourage the publication of General media articles or their content with the aim of promoting their products, but may offer to provide educational material or review copy to ensure accuracy.
1.6 A Telephone hotline or website or other similar information service may be set up to provide general information useful to the public (e.g. deworming, travel, smoking cessation, etc) Such services must be general and may not include any product promotional information or personal medical advice.
1.7 Direct mailing of product promotional materials from Company to non-healthcare professionals is prohibited.
1.8 Activities with, or materials provided to members of the General Public must never be such as to bring discredit upon, or reduce confidence in the Pharmaceutical Industry. Such activities would be seen as a severe breach of the code of practice.

Medical representatives

Guidelines for Medical Representatives

1.1. Medical representatives should be adequately trained and should possess sufficient medical and technical knowledge to present the information on the company's products in an accurate, current and balanced manner and cognizant of all provisions in the code.
1.2. Medical representatives should at all times maintain a high standard of ethical conduct in the discharge of their duties.
1.3. Oral presentations as well as written or printed material must aim at accuracy, fairness, balance and good taste. No promotion should be used for off-label product claims.
1.4. Unfair or misleading comparisons, or comparisons implying a therapeutic advantage which is not in fact justified, must be avoided by medical representatives.
1.5. Medical representatives must not employ any inducement or subterfuge to gain a call; neither should any fee be paid to gain the call.
1.6. Medical representatives must take adequate precautions to ensure that medical products in their possession are secured and stored in accordance with the recommended storage conditions.
1.7. Companies must prepare and provide to medical representatives detailed briefing material on the technical aspects of any product which is to be promoted.

1.8. The practice of gaining or extending an interview on the pretext of carrying out a survey is to be avoided. This does not preclude the use of Medical representatives to obtain bona fide survey information.
1.9. Medical representatives must not use cross channel sales method by using doctor's name as purchaser in selling products to the drugstores.
1.10. Medical Representatives should dress professionally in business attire or uniform while performing their duties.
1.11. Medical representatives should ensure that the frequency, timing and duration of appointment, together with the manner in which they are made, are such as not to cause inconvenience to the doctors, pharmacists or nurses especially in the OPD.

Off Label Claims

Guidelines for treatment of off label claims

Off-Label Claims shall be made only within the framework provided by the Health Ministry and/or FDA guidelines of the respective countries.

Printed Promotion Materials

Guidelines for printed promotion materials

1.1 All printed promotion materials shall include:
1.1.1 Name of the Product i.e. brand name
1.1.2 Active ingredients with approved names where they exist
1.1.3 The name and address of the pharmaceutical company responsible for marketing of the product
1.1.4 Date of production of the promotion materials
1.1.5 Abbreviated prescribing information which should include an approved indication or indications for use together with the dosage and method of use
1.1.6 A succinct statement of contraindications, precautions and side-effects
1.2 All Printed promotion material shall be approved by the regulatory Affairs/ medical teams.
1.3 The materials shall be handed over to qualified and appropriate medical representatives.
1.4 The materials shall be handed over to Doctors or other qualified HCPs only.
1.5 The materials shall be duly considered for revision as and when necessary.

Brand reminders

Guidelines for brand reminders

1.1 A reminder shall be short advertisement which will include:

1.1.1 Name of the product

1.1.2 Simple description of indications to designate the therapeutic category of the product.

Product training & Promotion Material

Guidelines for Product training

1.1 Product training shall be conducted for materials to be presented to the doctors and other healthcare professionals.
1.2 Training programs to be documented and retraining dates to be assigned at such interval as may be necessary.
1.3 Educative material for the products shall be separate for doctors and for other HCPs.
1.4 Training shall be provided on the claims to be made for the products which are approved by the Medical team.
1.5 Training shall cover the presentation and other techniques for representing to the HCPs.
1.6 Medical representatives who are in receipt of such educative/ Promotion Material shall give it only to qualified and eligible Health Care Professionals.

Charitable donations to Hospitals

Guidelines for Charitable Donations to Hospitals

1.1 Mega Lifesciences allows charitable donations to Hospitals for betterment of the society and to aid the public healthcare system considering the countries we work.
1.2 The Charitable Donations shall not be approved by the business head proposing the donation.
1.3 The Charitable Donations shall not be made with the intention of improved business prospects.
1.4 The Accounting team shall not account for such expenses as promotion expense.
1.5 The team shall request for a genuine receipt/ certificate for donation made.
1.6 Donations shall be requested and paid as per the form included in the Anti-Bribery Policy.

Form for approval of Charitable Donation under this policy.

Name of the Requesting Person:
Designation and Department:
Name of the Proposed Recepient:
Purpose of the Donation:

Electronic materials, Audio Visuals including Digital Media

Guidelines for Audio visuals including Digital Media provided to HCPs

1.1 The identity of the pharmaceutical company and of the intended audience should be readily apparent
1.2 The content should be appropriate to the intended audience
1.3 The presentation (content, links, etc) should be appropriate and apparent to the intended audience
1.4 Country specific information should comply with country laws and regulations.
1.5 The documents on such media shall not present any information which is contrary to indications included in the product inserts/ labels approved by the FDA of the country in which it is registered.

Symposia and Congresses

Guidelines for Symposia and Congress arranged by the Company or if the company sponsors participation in a Symposia/ Congresses arranged by a third party

1.1 The Company may arrange symposium or congress and invite a speaker for the same and sponsor key healthcare professionals to attend the event.
1.2 Attainment of scientific knowledge shall be the key objective.
1.3 The event can be arranged within the country or outside the country.
1.4 The location shall be such that is reasonably equipped for such events and the choice of the location shall be made based on facilities and other factors contributing to the suitability.
1.5 Company shall sponsor the expenses for travel and stay for the HCPs and not for any person accompanying person.
1.6 The participants shall spend minimum 75% of the time for such participating in such events.
1.7 The Company shall not pay any per diem / loss of practice allowance to the participants.
1.8 The event can be hosted in a foreign country if the facilities do not exist in the country or if the participants/ speakers are from different countries.
1.9 The company shall maintain valid documents for payment of speaker fees indicating the reasonability and the receipt of such money by the speaker. The fees shall be reasonable and there shall exist a reasonable need for the same. The number of speakers shall be as necessary.
1.10 Meetings shall be conducted as per Agenda circulated.

1.11 Company shall avoid extravagant venues and no standalone entertainment shall be provided.

1.12 Sponsorship of participants for any event conducted by the company or by 3rd party shall not be seen as a means to improve business prospects.

1.13 The expenses shall be documented and approved as per form attached below.

Form and Procedure for requesting travel expenses

Mega shall allow the Travel and Lodging expenses related to Government Officials/ HCPs subject to the following conditions:

a) The expense should be directly related to Mega's products or inspection of Mega's facilities by the Government Official or a conference/ seminar/ symposium organized by Mega.

b) The expense should be recorded appropriately in the accounting records.

c) The expense should be reasonable and customary.

d) The expense should not be unduly influence

e) Should be given openly and officially

The expenses shall be submitted for approval by the Managing Director and should be sent to the Compliance team as a report. The expense can be incurred only for the Government Official/ HCP and not for their spouse, children or other family members/ friends.

The transportation shall be Economy class air fare unless if it is a high ranking official/ reputed professional for whom it is customary to travel by Business class.

The Government Official/ HCP shall be entitled to room service including mini-bar to the extent of the limits for hospitality in this policy and shall not be entitled to long distance telephone calls, television pay per view services.

Mega does not provide Per Diem allowance for such travel exceeding the limits defined in the policy and that too for bona fide expenses and not with the intent to unduly influence.

The requesting business head shall fill a form for such payment as laid out in the form attached below.

Sr. No.	Name of the Government Official/ HCP	Purpose of Travel	Designation including Organization.	Ticket Cost	Hotel Cost

I confirm that the air fare shall be as per the policy and the hotel expenses shall not include the cost of pay per view television. The policy has been communicated to the concerned individuals.

……. ……

Requested By Approved By