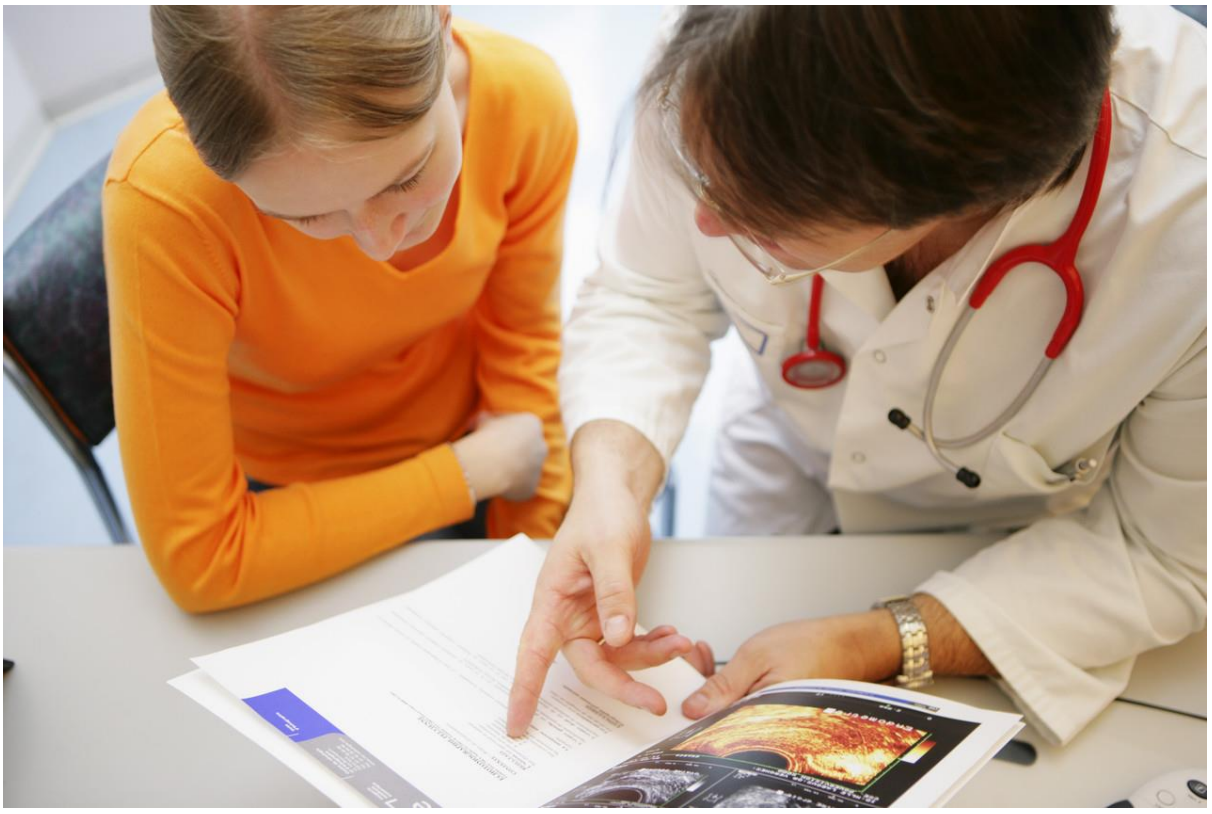
Moderator's Note – not for distribution

IFPMA Code Workshop
Hands on Compliance Training

Interactions with HCPs

Part 2: Gifts and Other Items



IFPMA

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General Instructions

Delegates will work in groups. Each group will receive an email which has come to the company in which you are employed.

You should:

1) Draft an appropriate outline reply to the email. You should list the main points that should be made in your response. You are not expected to create a beautifully crafted letter. Your response should be clear as to whether you agree to the requests contained in the letter and appropriate reasons should be given in making reference to applicable codes and legislation.

2) Create a check list that will guide a company's standards and procedures with respect to the subject area of the email you have received. You should list the key elements of a company's internal rules (policies & standards) and procedures (for review, approval, training and archiving etc) that must be in place. So, we are NOT asking you to write the actual standards or procedures, but just to list the elements that must be in place as part of a robust compliance structure to address requested such as the ones outlined in the scenario.

You should create a single slide/overhead/page for your response to each of the above tasks for the feedback session.

Each group will be asked to feed back on just one email but please familiarise yourselves with the emails the other groups will be considering and, if time permits, begin to discuss them.

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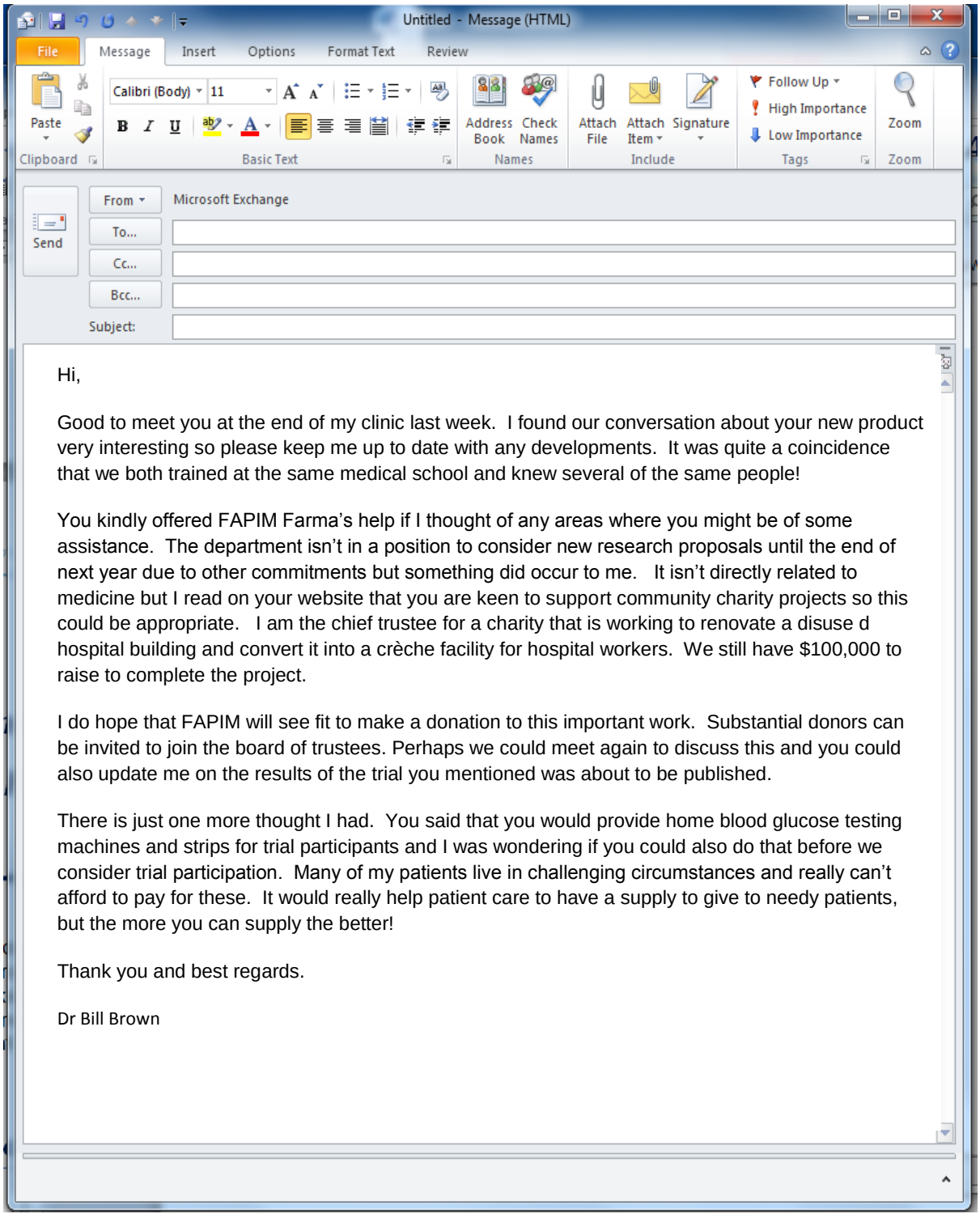
Group 1: You have an email from a leading national medical thought leader



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Group 1: You have an email from a leading national medical thought leader

This exercise brings the complications of personal friendships and interactions with the company medical department into consideration of what gifts etc are appropriate under the code. These factors should not affect acceptability under the code.

Outline reply to the email

Some points that might be included:

- Company is committed to being a good corporate citizen and supporting worthy causes.
- Donations can only be made in line with the company written policy
- I will refer the request to a separate department that deals with these matters
- Decisions cannot be linked to business relationships – we should keep the possible donation separate from any possible relationship concerning clinical trials
- It might be inappropriate for the company to become involved with the project by sitting on the board as suggested.
- It might be possible to provide items for patient use such as blood glucose monitors to support patient welfare but this arrangement should not be linked to our business activities. Also it should be limited in scope so it isn't of such a level to distort normal purchase and supply of these items by the hospital.
- Some relevant IFPMA Code clauses:
  - 7.5.1 – personal gifts
  - 7.5.3 Items of Medical Utility

Company's standards and procedures check list

Some points that might be included:

- Does the company have a donations policy?
- Does the policy state clearly the principles on which donation requests will be made? Does it expressly prohibit links to factors such as prescribing potential, possible business relationships etc.?
- Does the company have a standard operating procedure for handling donations requests?
- Does the approval procedure take responsibility away from the 'front line' to appropriate management? Does it ensure that all responses are properly documented?
- Do company standards and procedures apply to R&D and clinical departments? And do they know it?
- Have all those personnel been properly trained and kept up to date on the controls that apply?
- Is the application of the policy and SOP monitored?

Are financial systems robust enough to prevent or identify inappropriate payments such as budget holders misdirecting money for inappropriate and unbudgeted purposes?

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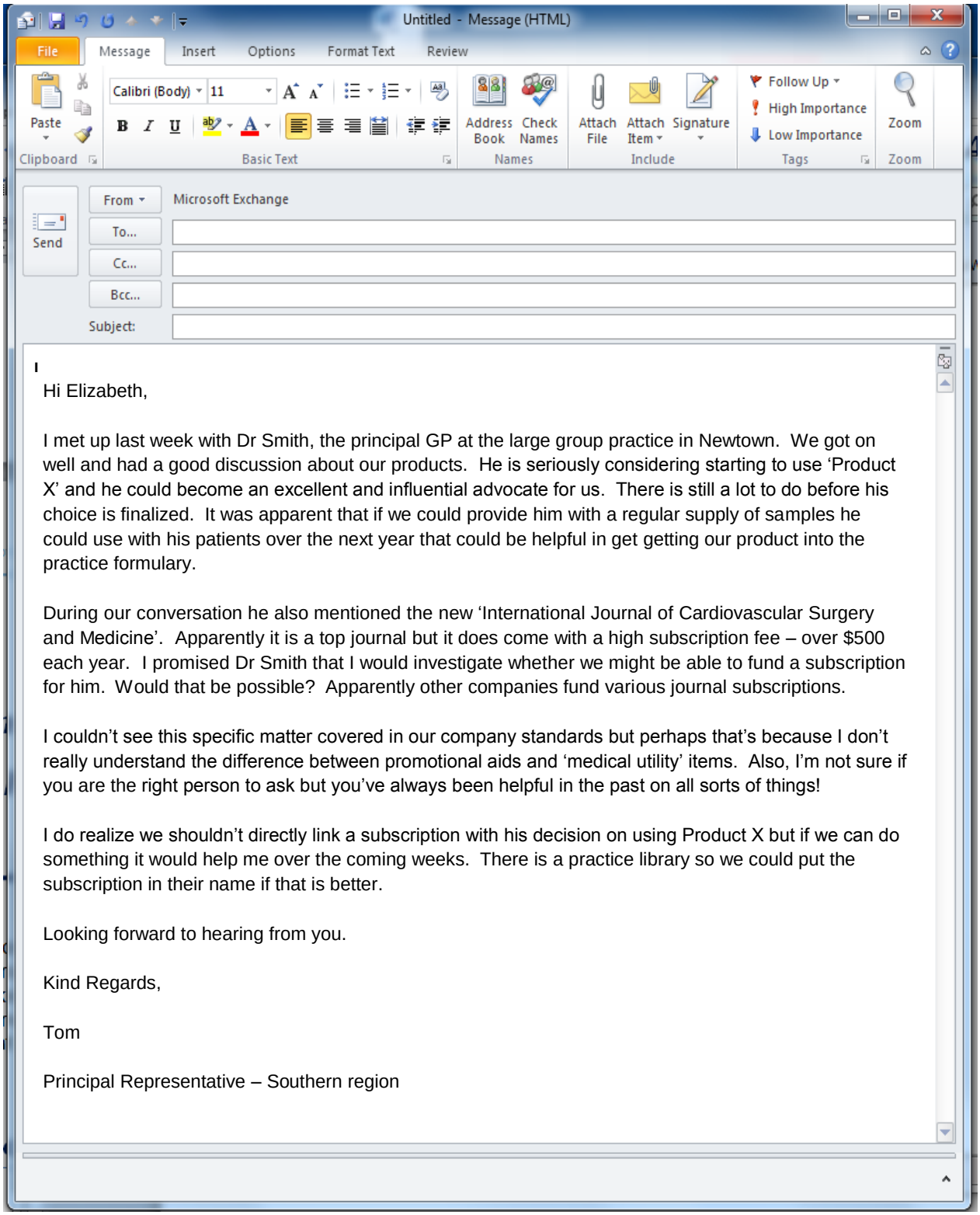
Group 2: You have an email from one of your company's representatives.



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Group 2: You have an email from one of your company's representatives.

This exercise highlights the role of representatives as being to promote and sell the company's products and avoiding providing personal benefits to prescribers in order to encourage such prescribing. It also prompts discussion of the use of samples and application of local rules.

Outline reply to the email

Some points that might be included:

Samples:

- Code and regulation controls on samples vary between countries. The reply to Elizabeth must reflect the local rules.
- It is unclear whether the requested supply really qualifies as 'samples'. Although they are likely to enhance patient care (as the code requires) many national codes might classify the regular supply as free goods rather than samples. Many national codes or regulations set specific limits on the number of samples that can be provided and/or for how long they may be supplied.
- Whether they are free goods or samples the arrangement does seem to be an incentive to prescribe Product X. There is an implication that the supply will be terminated if regular prescribing of product X doesn't happen. This would therefore be prohibited by the code clause that prohibits gifts that personally benefit the HCP.
- Samples must be marked 'so that they cannot be resold or otherwise misused' so providing unmarked sales packs as samples would not be permitted
- Samples may only be provided to HCPs authorised to prescribe the product. However this probably doesn't preclude them being given to administrative staff who are responsible for keeping medicines on behalf of the HCP. They should however be addressed for the attention of the prescriber who has requested them In most countries a sample request signed by the HCP would be needed.
- Some relevant IFPMA clause:
  - Clause 8: Samples
  - Clause 7.5.1 Personal Gifts

Journal subscription:

- Elizabeth acknowledges that the code does not allow benefits for the HCP to be linked to promotion and prescribing. Remind her that this also applies to implied links as well as explicit ones.
- A journal subscription is a benefit and the decision on whether to fund it must be totally separate. It will be referred to the grants/donations team without reference to the HCP or his group practice's potential commercial benefit to the company.
- A journal subscription can be considered as an item of medical utility that ultimately benefits patients. It would be better (and national codes may have specific rules on this) that the subscription is made to the practice library rather than to an individual HCP. The value must be in line with any local or company limits.
- Some relevant IFPMA Code clauses:
  - 7.5.1 – personal gifts

- 7.5.3 Items of Medical Utility

Company's standards and procedures check list

Some points that might be included:

- Company procedures should set out the circumstances under which samples and free good might be provided.
- Proper systems of control and accountability of samples must be in place with appropriate dcumentation. This should cover aspects such as stock control, recording to whom they are given, ensuring proper storage (security, storage conditions etc)
- The email suggests that the company standards and procedures and/or representatives' knowledge and training on them are inadequate. A review of the compliance programme supporting representatives and the relevant standards documents would be appropriate.
- The company could consider initiating a help line/email address where all employees can go for advice. An intranet area and/or widely distributed printed copies of standards and procedures could be provided.
- The company should consider a continuing programme of compliance support activities directed at representatives and sales management. Delegates can discuss what elements might be included.
- SOPs should be checked to ensure that the responsibilities for approving requests that representatives have are set out clearly. All requests should be clearly documented.

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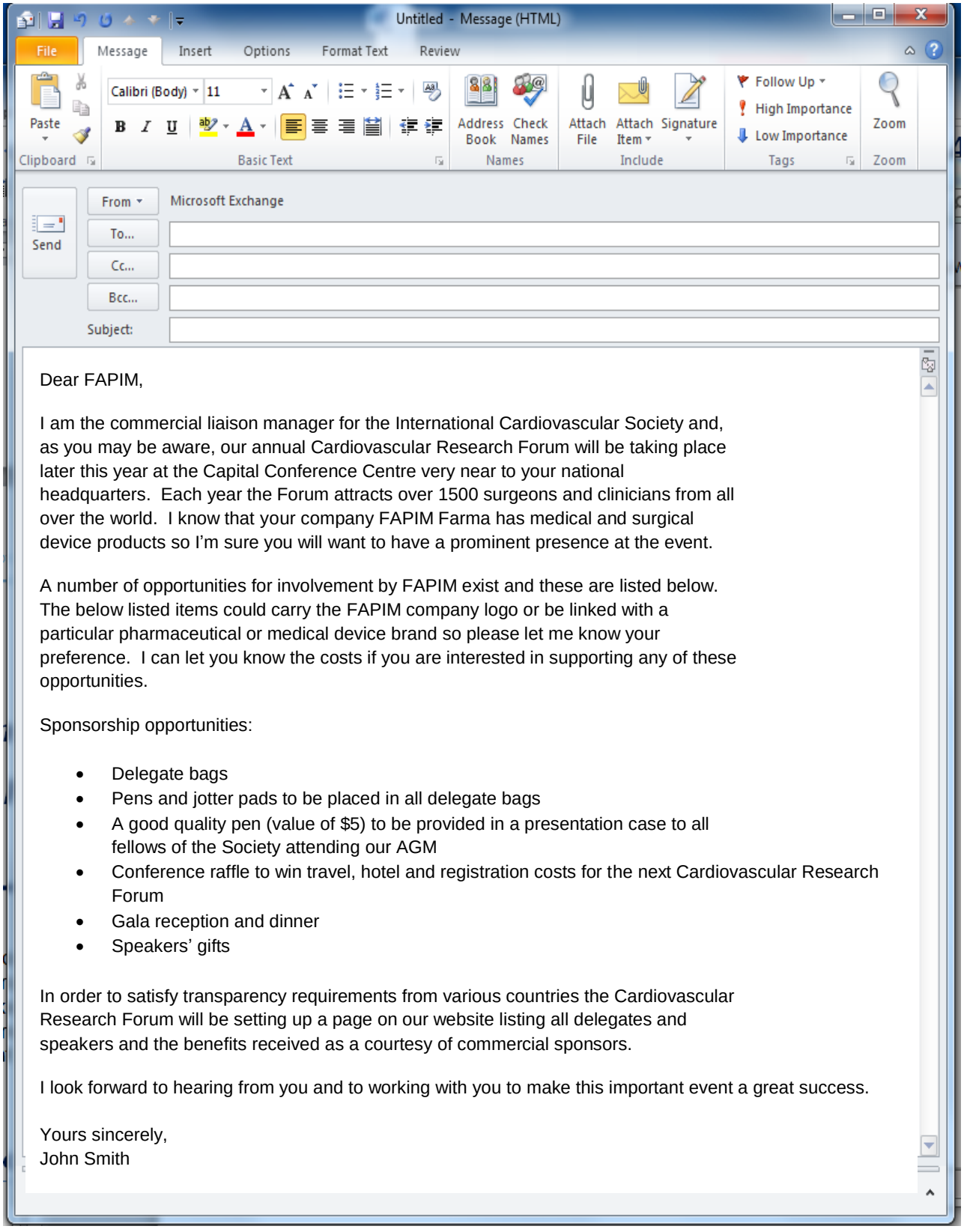
Group 3: You have an email from a medical conference organizer



Dear FAPIM,

I am the commercial liaison manager for the International Cardiovascular Society and, as you may be aware, our annual Cardiovascular Research Forum will be taking place later this year at the Capital Conference Centre very near to your national headquarters. Each year the Forum attracts over 1500 surgeons and clinicians from all over the world. I know that your company FAPIM Farma has medical and surgical device products so I'm sure you will want to have a prominent presence at the event.

A number of opportunities for involvement by FAPIM exist and these are listed below. The below listed items could carry the FAPIM company logo or be linked with a particular pharmaceutical or medical device brand so please let me know your preference. I can let you know the costs if you are interested in supporting any of these opportunities.

Sponsorship opportunities:

- Delegate bags
- Pens and jotter pads to be placed in all delegate bags
- A good quality pen (value of $5) to be provided in a presentation case to all fellows of the Society attending our AGM
- Conference raffle to win travel, hotel and registration costs for the next Cardiovascular Research Forum
- Gala reception and dinner
- Speakers' gifts

In order to satisfy transparency requirements from various countries the Cardiovascular Research Forum will be setting up a page on our website listing all delegates and speakers and the benefits received as a courtesy of commercial sponsors.

I look forward to hearing from you and to working with you to make this important event a great success.

Yours sincerely,
John Smith

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Group 3: You have an email from a medical conference organizer

This exercise provides an opportunity to discuss the need for local Signatory approval of international events taking place in a particular country. This is linked to specific opportunities to provide gifts and benefits.

Outline reply to the email

Some points that might be included:

- Our local compliance officer / Signatory will check out the acceptability under the local code of each of the options.
- The provision of delegate bags paid for by the company and carrying the company logo is likely to be acceptable. Similarly the provision of pens and pads. The IFPMA Code allows the provision of promotional aids providing these are of minimal value and relevant to the professional practice of healthcare professionals. Low cost pens are generally held to be acceptable so providing there are no local rules that prohibit product-branded promotional aids they will be acceptable for general distribution. Local code bodies often give guidance on the interpretation of 'minimal value' and 'relevance to healthcare practice'.
- It may be that in some countries a pen with a value of $5 is considered to be of 'minimal value'. However the distribution of higher value pens links their provision with individuals of high future prescribing potential or influence and this is likely to be not acceptable. (clause 7.5.2)
- Sponsoring the conference raffle to win travel, hotel and registration costs for the next Cardiovascular Research Forum is likely to be unacceptable. The cost will be high and sponsoring raffles is unlikely to be appropriate.
- Gala reception and dinner: Companies may only provide meals and refreshments that are incidental to the main purpose of the Event and are moderate and reasonable as judged by local standards . (clause 7.1.5). The description 'Gala Dinner' does not give the impression that it would be acceptable under the code. No entertainment or other leisure or social activities should be provided or paid for by member companies and Gala dinners may include such activities therefore ruling out company sponsorship.
- Speakers Gifts: Companies may engage speakers to talk at meetings and this is subject to a written contract and a fair market value fee (clause 7.4). They may not provide HCPs with personal gifts (clause 7.5.1). It therefore seems that sponsoring speakers' gifts would not be allowed.

Company's standards and procedures check list

Some points that might be included:

- Do the company's standards and approval operating systems cover adequately international conference activities? Is the relationship between national and international signatories' responsibilities clear?
- Do company standards and guidance set out clearly what activities and items may be sponsored at meetings?

- Transparency requirements: The IFPMA code does not include specific disclosure requirements but increasingly national requirements are being put in place. The company must ensure that the applicable national requirements are complied for with respect to delegates and speakers they sponsor. Companies should check that their standards and procedures adequately cover this area internationally.