Bristol Myers Squibb™

EMEA SPEAKER BRIEF

Commitment to ethics and integrity

Bristol-Myers Squibb (**BMS**) is committed to the highest standards of ethics and integrity and recognises the high expectations of honesty and transparency placed on companies in our industry. BMS understands that you are also required to comply with applicable laws, regulations and professional codes – many of which are similar to or mirror the rules which apply to BMS. BMS does not want to change or impact your obligations, but simply to explain the additional rules which apply to the presentations sponsored by the pharmaceutical industry.

BMS is not seeking to control or influence your opinions, but to assist in compliance with the additional legal and regulatory requirements that apply to BMS sponsored presentations. This Speaker Brief and the BMS agreement that all parties sign are designed to:

- document the services you will provide in exchange for the agreed honoraria and reasonable expenses;
- set out the parties' expectations and agreements with respect to how the services will be delivered;
- ensure transparency to protect both you and BMS from any misinterpretation of the relationship or and any suggestion that the fees constitute an inappropriate form of inducement;
- explain the relevant laws and regulatory requirements relating to the pharmaceutical industry to facilitate compliance by both parties; and
- explain BMS' policies and procedures which apply to BMS sponsored presentations.

Accordingly, when presenting at an event that is sponsored and paid for by BMS, BMS asks that you comply with this Speaker Brief and the terms of BMS' agreement with you.

The legal and regulatory framework

The EFPIA Code of Practice, the Middle East Code of Practice and related national country codes or guidelines which adopt the EFPIA Code (Codes) govern the promotion of prescription only medicines to health care professionals and set out guidelines on various non-promotional activities as well. The Codes are the key source of rules applying to the pharmaceutical industry as they establish a stringent self-regulatory environment or standard and set out the requirements of European or other applicable laws.

The Codes contain detailed provisions that are designed to ensure that pharmaceutical companies operate in a responsible, ethical and transparent manner.

Promotional Activities

The definition of promotion is broad and regulates any activity conducted by BMS or with its authority for the purpose of encouraging the prescription, sale, administration, supply, recommendation or consumption of

BMS products. In this context, presentations which are organised and paid for by BMS relating to an in-label discussion of BMS products would be considered promotional under this definition.

Non-Promotional Activities

BMS also conducts a number of non-promotional activities which are governed by the Codes and which if implemented appropriately, are not considered promotion but the legitimate exchange of scientific information. These include satellite symposia at international or national congresses, disease only related education or advisory board activities.

Consistent with BMS' commitment to ethics and integrity, presentations sponsored by BMS need to comply with all applicable laws and regulations, including the Codes. Copies of the relevant Codes are available on request from your BMS contact or may be downloaded from the internet.

Additional Employer or Professional Association Consents (where applicable)

In some countries, additional legal or regulatory requirements are required to ensure transparency between health care professionals and the pharmaceutical industry. This may include for example, obtaining employer consent prior to delivering the Services for publicly employed physicians or notifying the relevant Physicians council or industry association of the proposed fee and speaker arrangements in advance. If this is required by the laws of your country, then BMS will facilitate the approvals of the Physicians council or industry association but asks you to obtain any employer's consent that may be required. A copy of such approval must be provided to BMS as promptly as possible.

Conflict of Interest

You, as Speaker, are solely responsible and liable to check whether there is any potential conflict of interest which would prevent you from providing the Services in accordance with the contemplated agreement. It is your responsibility to notify BMS in case of any potential conflict of interest before entering into an agreement and to clear any such conflict before executing such an agreement. If a conflict of interest remains, no agreement will be entered into with you and BMS. This includes without limitation any conflict of interest with your employer, a government authority, the national health service, any medical institution/ organization/ association or other whether such conflict of interest is of labour, contractual or other nature according to applicable laws.

Developing your presentation

As stated above, BMS is responsible for ensuring compliance with the Codes for presentations sponsored and paid for by BMS and so BMS needs to review your presentation for this reason. Such review must be performed before the presentation is delivered.

To facilitate the review process, BMS has 'pre-approved' clinical and scientific slide sets and other materials that you can use in your presentation. To ensure compliance with the Codes and timely and efficient development of your presentation, BMS encourages you to use pre-approved materials.

When using your own materials or slides, you are required to submit a copy of your presentation to BMS in advance of the meeting and to perform a presentation rehearsal, where applicable. Please identify your own slides to distinguish them from pre-approved slides. This is also important for you since under the terms of the agreement you or the relevant third party, will continue to own those slides which you provide. As stated above, BMS is responsible for ensuring compliance with the Codes for presentations sponsored and paid for

by BMS and so BMS needs to review your presentation for this reason. Such review must be performed before the presentation is delivered.

Practical requirements in the context of promotional and non-promotional activities

- For transparency reasons, BMS' involvement with the presentation must be clear to the audience and the Codes require that sponsorship of both **promotional and non-promotional** meetings is declared. The presentation should therefore be clearly and prominently labelled as "Sponsored by Bristol-Myers Squibb", "Supported by Bristol-Myers Squibb",, the BMS logo or something similar. In the case of products co-promoted or marketed in conjunction with other pharmaceutical companies, sponsorship by those other companies should be clearly and prominently labelled.

For non-promotional meetings, example title slide

Presentation Title

Name, Title and Affiliation of Speaker
[Date]

Context of event [eg BMS Satellite Symposia at ### Congress]

Sponsored by Bristol-Myers Squibb

BMS ref: ##
Date of preparation: [date]

For promotional meetings, example title slide

Presentation Title

Name, Title and Affiliation of Speaker
[Date]

Context of event [eg BMS Satellite Symposia at ### Congress]

Sponsored by Bristol-Myers Squibb

- In the context of **promotional activities**, information about a BMS product may only relate to its licensed indications and be consistent with the Summary of Product Characteristics (**SmPC**) or equivalent regulatory document if outside the EU. Your BMS contact can address any questions you may have about the list of indications that are licensed or consistent with the relevant SmPC.

  This means that it is not possible to present unlicensed or inconsistent product information or for "back-up slides" to be presented. You must not initiate or encourage any discussion or questions regarding any unlicensed uses, doses or any information that is not consistent with or that is contrary to the SmPC or equivalent regulatory document if outside the EU. If during a meeting unsolicited off-label questions are raised by audience members, BMS requires you to:

  - Direct the audience member to submit the inquiry to BMS Medical which can be accomplished by providing the BMS Medical Information contact details, or

  - Direct the audience member to a BMS Medical employee present during the meeting

  However, if, you wish to respond to that question from your own experience, we ask you to do it in a succinct manner and clearly state the following:

    – The information is not licensed or consistent with the SmPC or equivalent regulatory document if outside the EU.

    – Your response is your opinion and not that of BMS.

    – BMS does not recommend or endorse use of BMS products that are unlicensed or is inconsistent with the SmPC or equivalent regulatory document if outside the EU.

- With the exception of such responses, information related to unlicensed or inconsistent indications of a BMS product may only be discussed in the context of **non-promotional activities** if discussed in a fair, balanced manner and where appropriate to the meeting content. However, if the discussion is not fair and balanced, then Codes would consider such activities as disguised promotion or pre-licence promotion contrary to the rules. The BMS approval process is designed to ensure that this does not inadvertently occur. However, again, we ask to you to clearly state the following:

    – The information is not licensed or consistent with the SmPC or equivalent regulatory document if outside the EU.

    – You are expressing your opinion and not that of BMS.

    – BMS does not recommend or endorse use of BMS products that are unlicensed or is inconsistent with the SmPC or equivalent regulatory document if outside the EU.

- The presentation must not infringe the rights of others, e.g. copyright, breach of confidentiality or trademarks.

- The presentation must not include personal or sensitive personal data.

- The presentation must be in good taste and not capable of causing offence to members of the audience.

- The presentation must not be unfair, unbalanced, offensive, pejorative or disparaging in any way (whether in general, in relation to BMS or its products, to another company or its products, etc),

- All information, claims and comparisons about BMS or competitor products must be:

  – Accurate, balanced, fair, objective and unambiguous.

  – Up-to-date.

  – Capable of substantiation (for any comparison, at least one well-controlled head to head study must be available).

  – Referenced (generally the primary reference should be cited). Hard copies of the references do not need to be submitted to BMS unless BMS receives a request for substantiation and does not have a copy of the relevant reference.

  – Brand names of competitor products must not be used in presentations unless the prior consent of the companies concerned has been obtained. In practice, this means that the use of brand names of non-BMS products should be avoided.

  For promotional meetings, the SmPC or abbreviated prescribing information or equivalent regulatory document if outside the EU and in some countries, a statement regarding adverse event reporting, must be included in a presentation that references and makes claims about a BMS product. BMS will provide you with the relevant information that is required but at a minimum, the availability of the SmPC or the prescribing information or equivalent regulatory document if outside the EU must be clearly and prominently stated on the first slide of the presentation.

- BMS' competitors and their products must be discussed in a fair, balanced and accurate manner.

This list includes key requirements of the Codes but is not exhaustive. You should familiarise yourself with the Codes' requirements to ensure compliance. If you have any questions about the Codes or your obligations, then your BMS contact will be happy to help.

Substantiation of your presentation after the event

The Codes require that BMS substantiate any information, claim or comparison contained in your presentation as soon as possible after a request for substantiation.

This means that information contained in your presentation must be publicly available and clearly and unambiguously referenced. If BMS receives a request for substantiation of a statement presented by you, BMS will contact you for a copy of the relevant reference (except in the case of pre-certified slides where BMS already has substantiating material for all such slides).

Your presentation is intended to be used only during the event described in the agreement and shall not be used again unless otherwise agreed by BMS.