



**Association of
British Healthcare Industries**

**CODE OF
BUSINESS PRACTICE**

FEBRUARY 2009

Contents

3	ABHI Code of Business Practice
4–5	Specific Policies
6–13	APPENDIX 1 ABHI Guidelines on Interactions with Health Care Professionals
14–21	APPENDIX 2 Q&A on the ABHI Guidelines on Interactions with Health Care Professionals
22–29	APPENDIX 3 ABHI Competition Law Compliance Guidelines ANNEX 1 Dos and Don'ts ANNEX 2 Exchanging Data and Information
30–31	APPENDIX 4 ABHI Procedure for Resolution of Complaints received under the ABHI Code of Business Practice

ABHI Code of Business Practice

ABHI is an association representing the interests of UK medical technology/device manufacturers. ABHI believes that high quality, cost-effective medical technologies and related services can make a significant contribution to the safety and well being of patients and the improvement of healthcare systems.

ABHI's members recognise that compliance with applicable laws and regulations and adherence to ethical standards are both an obligation and a critical step to the achievement of the aforementioned goals and can enhance the reputation and success of the medical technology/device industry.

This Code of Business Practice (hereinafter referred to as the 'Code') is intended to provide guidance as to the minimum standards which should apply to its members' business practices in the UK, Europe and, generally, elsewhere. It is not intended to supplant or supersede national laws or regulations or other professional or other business codes (including company codes) which may apply to its members.

The Code and its associated documents are based on the Eucomed Code of Business Practice, ABHI having been closely involved in its development.

Specific Policies

Quality and Regulatory Compliance

ABHI's members are committed to the production and supply of high quality medical devices and related services in the interest of patient safety and well-being.

Members should comply with the legal and regulatory requirements of the countries where they do business. These include both regulations specific to medical devices and general legal requirements applicable to the medical device and other industries.

The following paragraphs are not intended to be an exhaustive list of requirements but they do highlight areas of particular relevance to the medical device industry.

Interactions with Health Care Professionals

Compliance with applicable laws and adherence to ethical standards are important to the medical technology/devices industry's ability to continue to collaborate effectively with health care professionals. Such collaboration can take the form of:

- Developing medical technologies.
- Providing training, education, service and support to enable the safe and effective use of medical technologies; and
- Supporting medical research, education, and enhancement of professional skills.

These activities are necessary to advance medical science, improve patient care.

To ensure ethical interactions with individuals or entities that purchase, lease, recommend or use members' products, members should duly consider the ABHI Guidelines on Interactions with Health Care Professionals (Appendix 1).

Advertising and Promotion

Members should ensure that all promotional presentations, including product claims and comparisons, are accurate, balanced, fair, objective and unambiguous. They should be justified by appropriate evidence. Statements should not mislead the intended audience.

Unlawful Payments and Practices

Members should not directly or indirectly offer, make, or authorize payment of money or anything of material value, to unlawfully (a) influence the judgment or conduct of any individual, customer, or company; (b) win or retain business; (c) influence any act or decision of any governmental official; or (d) gain an advantage. This requirement extends not only to direct inducements, but also to indirect inducements made by a member in any form through agents, consultants or other third parties. Members should have particular regard to laws and regulations prohibiting or restricting inducements aimed at influencing clinicians or customers.

Competition/Antitrust and Procurement Laws

Members should conduct their business activities in accordance with the requirements of applicable competition and public procurement laws. Prohibited activities may consist of: (a) agreements or understandings with competitors to fix prices, allocate customers or territories or restrict sales; (b) exchange of pricing or other confidential information with competitors; and (c), price discrimination or refusals to sell. Members should duly consider the ABHI Guidelines on Competition Law (Appendix 3).

Export Controls and Sanctions

Members should ensure compliance with applicable export control laws and other rules restricting trade with certain countries.

Environmental Issues

Members should conduct their business in compliance with all applicable environmental laws and regulations.

Data Privacy

Members should ensure that patient data and other types of confidential or personal data be maintained and used in accordance with applicable legal requirements.

Compliance and Enforcement

Members should take measures to ensure compliance with the principles of this Code by their employees, agents and representatives. Members should adopt effective compliance programs by issuing written policies and procedures, and in the case of corporate members, by conducting training programs and implementing clear procedures, controls and enforcement mechanisms.

ABHI reserves the right as a last resort – in application of the relevant provisions or principles of its statutes – to withdraw membership from any member that ABHI is convinced, does not follow the principles of this Code of Business Practice.

ABHI Guidelines on Interactions with Health Care Professionals

Preamble

These guidelines are intended to provide guidance on the interactions of ABHI members with individuals (clinical or non-clinical, including but not limited to, physicians, nurses, technicians and research co-coordinators) or entities (such as hospitals or group purchasing bodies) that directly or indirectly purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe members' medical devices ('Health Care Professionals').

There are many forms of interactions between ABHI members and Health Care Professionals that advance medical science or improve patient care, including:

- **Advancement of Medical Technology:** The development of innovative medical devices and the improvement of existing products require collaboration between members and Health Care Professionals. Innovation and creativity are essential to the development and evolution of medical devices, often occurring outside the facilities of medical device companies.
- **Safe and Effective use of Medical Technology:** The safe and effective use of medical technology requires members to offer Health Care Professionals appropriate instruction, education, training, service and technical support. Regulators may also require this type of training as a condition of product approval.
- **Research and Education:** Members' support of *bona fide* medical research, education, and enhancement of professional skills contribute amongst others to patient safety and increase access to new technology.

ABHI members recognise that adherence to ethical standards and compliance with applicable laws are critical to the medical technology/devices industry's ability to continue its collaboration with Health Care Professionals. Members must encourage ethical business practices and socially responsible industry conduct related to their interactions with Health Care Professionals.

Members must continue to respect the obligation of Health Care Professionals to make independent decisions regarding treatment.

The guidelines are based on the following key principles:

- The Principle of Separation: Interaction between industry and Health Care Professionals must not be misused to influence through undue or improper advantages, purchasing decisions, nor should such interaction be contingent upon sales transactions or use or recommendation of members' products.
- The Principle of Transparency: Interaction between industry and Health Care Professionals must be transparent and comply with national and local laws, regulations or professional codes of conduct. In countries where specific provision is not made, members shall nevertheless maintain appropriate transparency by requiring prior written notification is made to the hospital administration, the Health Care Professional's superior or other locally-designated competent authority, fully disclosing the purpose and scope of the interaction.
- The Principle of Equivalence: Where Health Care Professionals are engaged by a member to perform a service for or on behalf of a member, the remuneration paid by the member must be commensurate with, and represent a fair market value for, the services performed by the Health Care Professional.
- The Principle of Documentation: For interactions between a member and a Health Care Professional, such as where services are performed by a Health Care Professional for or on behalf of a member, there must be a written agreement setting out, *inter alia*, the purpose of the interaction, the services to be performed, the method for reimbursement of expenses as well as the remuneration to be paid by the member. The activities envisaged by the agreement must be substantiated and evidenced by activity reports and the like. Adequate documentation such as the agreement, related reports, invoices etc. must be retained by the member to support the need for, and materiality of, the services as well as the reasonableness of the remuneration paid.

Members should require that third-party intermediaries, both sales intermediaries and other third-party agents, including but not limited to consultants, distributors, sales agents, marketing agents, brokers, missionary commercial agents and independent sales representatives, who interact with Health Care Professionals in connection with the sale, promotion or any other activity involving members' products, comply with standards equivalent to these guidelines. Accordingly, it is recommended that where such arrangements are entered into, the relevant contractual documentation imposes obligations upon the third party to comply with these or equivalent guidelines.

These guidelines set out the standards appropriate to various types of relationships with Health Care Professionals. These guidelines are not intended to supplant or supersede national laws or regulations or professional codes (including company codes) that may impose more stringent requirements upon members or Health Care Professionals who engage in certain activities in those countries. All members should independently ascertain that their interactions with Health Care Professionals comply with all current national and local laws, regulations and professional codes.

Member-Sponsored Product Training and Education

Where appropriate, members should make product education and training available to Health Care Professionals to facilitate the safe and effective use of medical technology. Such education and training programmes should occur at appropriate locations taking account of the convenience of the attendees and the nature of the training. In particular:

- Programmes and events should be conducted in clinical, laboratory, educational, conference, or other appropriate settings, including members' own premises or commercially available meeting facilities that are conducive to effective transmission of knowledge and any required 'hands-on' training. The training staff should have the appropriate expertise to conduct such training.
- Members may provide attendees with reasonably priced meals in connection with the programme, and for educational programmes necessitating overnight stays, additional hospitality may be appropriate. Any hospitality should be reasonable in value, subordinate in time and focus to the educational purpose of the training and in compliance with the regulations of the country where the Health Care Professional is licensed to practise.
- Members may pay for reasonable travel and accommodation costs incurred by an attending Health Care Professional, in compliance with the regulations of the country where the Health Care Professional is licensed to practise.
- Members are not permitted to facilitate or pay for meals, travel, accommodation or other expenses for spouses or guests of Health Care Professionals, or for any other person who does not have a *bona fide* professional interest in the information being shared at the meeting.

Supporting Third-Party Educational Conferences

Bona fide independent, educational, scientific or policy-making conferences promote scientific knowledge, medical advancement and assist in the delivery of effective healthcare. To these ends, members may support such events provided the educational conference content promotes scientific knowledge, medical advancement and the delivery of effective healthcare and is consistent with relevant guidelines established by professional societies or organisations for such meetings.

ABHI members may support such events by the provision of financial, scientific, technical, organisational and/or logistical assistance as follows:

• Sponsorship of Health Care Professionals

Where permitted under national and local laws, regulations and professional codes of conduct, members may provide financial support to cover the cost of conference attendance by individual Health Care Professionals. Such financial support should be limited to the conference registration fee and reasonable travel, meals and accommodation costs relating to attendance at the event. Members must ensure full compliance with national and local laws with regard to the disclosure or approval requirements associated with such sponsorship and where no such requirements are prescribed, shall nevertheless maintain appropriate transparency, for example, by requiring prior written notification of the sponsorship is made to the hospital administration, the Health Care Professional's superior or other locally designated competent authority.

- **Advertisements and Demonstrations**

Members may purchase advertisements and lease booth space for company displays at conferences.

- **Conference Support**

Members may provide financial grants directly to the conference organiser to reduce the overall cost of attendance for participants and to cover reasonable honoraria, travel, meals and accommodation expenses of Health Care Professionals who are *bona fide* conference faculty members. A written request must be made by the conference organiser, to the member and any sponsorship must be paid directly to the conference organiser or training institution. The conference organiser alone is responsible for the programme content and the faculty selection. Members may not have any detailed involvement in determining the content of the conference other than recommending speakers or commenting on the programme where requested to do so.

- **Satellite Symposia**

Members may sponsor satellite symposia at third-party conferences and provide presentations on subjects that are consistent with the overall content of the third-party conference provided that all information presented is fair, balanced and scientifically rigorous. Members may determine the content of these events and be responsible for faculty selection. The arrangement must be documented by written contract and the support of the member must be disclosed in all materials relating to the satellite event.

- **Scholarships**

Members may also provide educational grants to training institutions, healthcare institutions or professional societies for medical education programmes by providing financial support for fellowships and similar scholarship awards. The selection of the grantee should be within the discretion of the institution at which they are enrolled or the teaching institution at which they will be trained. Grants must be provided to the teaching or professional institution, not to individual fellows, save at the prior written request of the institution. In no way should the funding be tied to an institution's purchase of a company's products, or otherwise be based on an institution's past or potential future use of the company's products or services.

Sales and Promotional Meetings

In the countries where it is appropriate for members to meet with Health Care Professionals to discuss product features, conduct contract negotiations, or discuss sales terms, these meetings should, as a general rule, occur at or close to the Health Care Professional's place of business. In connection with such meetings, members may pay for reasonably priced meals for Health Care Professional attendees in an environment that is conducive to the exchange of information. Where plant tours or demonstrations of non-portable equipment are necessary, members may also pay for the reasonable travel and accommodation costs of Health Care Professional attendees. However, members are not permitted to facilitate or pay for meals, travel, accommodation or other expenses for spouses or guests of Health Care Professionals, or for any other person who does not have a *bona fide* professional interest in the information being shared at the meeting.

Arrangements with Consultants

Health Care Professionals may serve as consultants to members, providing meaningful *bona fide* services, including research, participation on advisory boards, presentation at member-sponsored training or third-party educational conferences, and product development. It is appropriate to pay Health Care Professionals reasonable compensation for performing these services. The following factors support the existence of a *bona fide* consulting arrangement between members and Health Care Professionals:

- Consulting agreements must be entered into only where a legitimate purpose for the services is identified in advance.
- Selection of consultants must be on the basis of the consultant's qualifications and expertise to address the identified purpose and should not be on the basis of volume or value of business generated by the consultant.
- Consulting arrangements with Health Care Professionals must be described in a written agreement, signed by the parties and must specify the services to be provided. Such arrangements must be consistent with the regulations of the country where the Health Care Professional is licensed to practise.
- The compensation paid to Health Care Professionals engaged as consultants must be the fair market value for the services provided and must not be tied in any way to the value of medical devices which the consultants may use for their own practice. All payments made must comply with applicable tax and other legal requirements. Members may pay for reasonable and actual expenses incurred by consultants in carrying out the subject of the engagement including reasonable and actual travel, meals and accommodation expenses incurred by consultants in attending meetings with or on behalf of members. The written agreement should describe all expenses that can be claimed by the consultant in relation to the provision of the services.
- Members must ensure full compliance with national and local laws with regard to the disclosure or approval requirements associated with members engaging Health Care Professionals as consultants. Where no such national requirements are prescribed, members shall nevertheless maintain appropriate transparency by requiring prior written notification is made to the hospital administration, the Health Care Professional's superior or other locally-designated competent authority, disclosing the purpose and scope of the consultancy arrangement.
- All consultancy arrangements with Health Care Professionals must be documented in writing even where the Health Care Professional does not require payment for services or where the arrangement involves a one-day event only.
- The venue and circumstances for member meetings with consultants should be appropriate to the subject matter of the consultation. The meetings should be conducted in clinical, educational, conference or other suitable settings, including hotel or other available meeting facilities, conducive to the effective exchange of information.
- Member-sponsored hospitality that occurs in conjunction with a consultant meeting should be modest in value and should be subordinate in time and focus for the primary purpose of the meeting.

- When a member contracts with a Health Care Professional acting as a consultant for research services, the written agreement described above must reference a written research protocol or written schedule of work as appropriate and all required consents and approvals should be obtained.
- When a member contracts with a Health Care Professional for the development of intellectual property, there must be a written agreement providing compensation at a fair market value. However, under no circumstances may the Health Care Professional receive any financial compensation in respect of medical devices he/she has prescribed in the past or may prescribe in the future, including medical devices which contain the novel intellectual property. All required consents and approvals should be obtained, including from the hospital administration or the Health Care Professional's superior (or locally-designated competent authority).

Gifts

Members occasionally may provide inexpensive, branded or non-branded items as gifts to Health Care Professionals, if they are modest in value and in accordance with the national and local laws, regulations and industry and professional codes of conduct of the country where the Health Care Professional is licensed to practise. Gifts must relate to the Health Care Professional's practice, benefit patients or serve a genuine educational function. Gifts must not be given in the form of cash or cash equivalents.

This section is not intended to address the legitimate practice of providing appropriate sample products and opportunities for product evaluation.

Provision of Reimbursement and other Economic Information

Members should support accurate and responsible billing to reimbursement authorities and other payers. In doing so, they provide economic efficiency and reimbursement information to Health Care Professionals and third-party payers regarding members' products. This information should be limited to identifying appropriate coverage, coding or billing of member products, or procedures using those products, or to encourage the economically efficient delivery of member products. This section is not intended to address the legitimate practice of providing technical or other support intended to aid appropriate use or installation of the member's products.

Donations for Charitable and Philanthropic Purposes

Members may make donations for charitable or other philanthropic purposes. Donations may be made only to charitable organisations or other non-profit entities entitled to receive them under applicable national or local laws and regulations. Donations may be made to support the general activities of a *bona fide* organisation or may be made to support general fund-raising drives for projects undertaken by such an organisation.

Charitable donations must not be tied in any way to past, present or potential future use of the member's products or services.

All donations to a charity or non-profit organisation should be appropriately documented. For example, a written request should be submitted by the charitable organisation, detailing the purpose of the charity and the nature of its activities. The payment should be made out in the name of the charity and paid directly to the charity. Charitable donations to a *bona fide* organisation should not be made in response to requests made by Health Care Professionals unless the Health Care Professional is an employee or officer of the organisation and submits the request on behalf of the organisation. It would not be appropriate for a member to support the favourite charity of a Health Care Professional in response to a request by that Health Care Professional.

Members should have no control over the final use of funds provided as charitable donations to Charities and other non-profit organisations.

Educational Grants

Members may provide funds to support genuine independent medical research, advancement of medical science or education, or patient and public education. However, it is important that support of these programmes and activities by members is not viewed as a price concession, reward to favoured customers or inducements to recommend, prescribe or purchase members' products or services. Therefore members should ensure that they maintain appropriate documentation in respect of all educational grants made.

Educational grants must not be tied in any way to past, present or potential future use of the member's products or services.

Educational grants may be made only to organisations or entities entitled to receive them under applicable national and local laws and regulations and should not be made to individual Health Care Professionals. (For guidance on how members may support the education of individual Health Care Professionals refer to page 8 Supporting Third-Party Educational Conferences).

Examples of appropriate educational programmes and related considerations are as follows:

- **Scholarships**
Professional organisations, hospitals and universities where Health Care Professionals are in training may be eligible to receive grants to support scholarships. For guidance on how members may support scholarships and similar awards refer to page 8 Supporting Third-Party Educational Conferences.
- **Advancement of Healthcare Education**
Members may support Health Care Professional education by donating funds to institutions or organisations for either accredited or non-accredited healthcare education. For further guidance on how members may support such education, refer to page 8 Supporting Third-Party Educational Conferences.
- **Research**
Research grants to support customer-initiated studies may be permitted for programmes involving clinical or non-clinical research in areas of legitimate interest to the member. The member may provide funds for documented expenses, in-kind services, or free products to support clearly defined *bona fide* research activities of Health Care Professionals where permitted by national laws, regulations and professional codes of conduct. All requests for

research grants must be in writing from the requestor stating the nature and objective of the research activity. No support should be provided until a written agreement is signed by both parties and said agreement should provide for adverse event reporting where appropriate. Full disclosure of the award must be made to the hospital administration, or the Health Care Professional's superior, or other locally-designated competent authority as appropriate and the recipient of the grant shall be required to acknowledge the member's support of the research in all oral or written presentations of the results.

- **Public Education**

Members may make grants for the purpose of supporting education of patients or the public about important healthcare topics.

Q&A on the ABHI Guidelines on Interactions with Health Care Professionals

- Q1. Under the guidelines, is written notification to the Health Care Professional's employer (or other locally-designated body) required for each interaction with a member? For example, is such notification required each time a member pays for a reasonably priced meal or gives a Health Care Professional a gift which is otherwise in line with the requirements of the guidelines?**
- A1.** Written notification to the Health Care Professional's employer (or other locally designated body) is required whenever a member engages a Health Care Professional as a consultant or whenever a member makes a financial contribution to the Health Care Professional's medical training. Incidental interactions arising in the normal course of business such as meals associated with educational or business meetings or the receipt of modest gifts related to the Health Care Professional's practice, do not require notification.
- Q2. Under the guidelines, what is meant by the term 'appropriate location'?**
- A2.** An 'appropriate location' is a recognised institution, conference or business centre which is centrally located, providing ease of access when regard is given to the place of origin of the invited participants. The location selected should not become the main attraction of the event and members must consider at all times the image that may be projected to the public by their choice of location.
- Q3. What criteria should a member apply when considering the country location of product training or education?**
- A3.** If the participants are primarily of one country, the venue should be in the specific country involved. If the participants are from multiple countries in Europe, then a European country affording ease of access for participants should be chosen. It is expected that the country selected is the residence of at least some of the participants of the meeting.

Q4. Can a member use a meeting venue outside Europe?

A4. Yes, provided the participants are from multiple countries outside Europe. If the participants are primarily from within Europe, the venue should be in Europe. It is expected that the country selected (and the state, if the location is in the United States) is the residence of at least some of the participants of the meeting.

Q5. Are hotels suitable venues for member-sponsored meetings with Health Care Professionals?

A5. Yes, hotels are suitable venues for member-sponsored meetings with Health Care Professionals. The hotel selected should not become the main attraction of the event and members must consider at all times the image that may be conveyed to the public by their choice of hotel. The hotel should not normally be a top category or luxury hotel in the country in which it is located nor be renowned for its entertainment facilities. An important factor in selecting a hotel is its suitability for business meetings, including the availability of conference facilities.

Q6. Can a member use a hotel that offers leisure facilities such as golf, or water sports for member-sponsored training and education?

A6. Many business hotels and conference centres provide leisure facilities and while it would not be reasonable to exclude these venues if otherwise appropriate, members must exercise caution. Members should arrange the meeting agenda such that Health Care Professionals attending the meeting would not be free to make use of the leisure and sporting facilities during any significant part of a normal working day. Further, where hotels require additional payment to enable guests to use the leisure and sporting facilities, members may not make such payments on behalf of the Health Care Professionals.

Q7. Are cruise ships or golf clubs appropriate venues for member-sponsored training and education?

A7. No. Cruise ships, golf clubs or health spas and venues renowned for their entertainment facilities are not appropriate venues and should not be used.

Q8. Under the guidelines, what do the terms 'reasonable' and 'hospitality' mean?

A8. The guidelines seek to find a balance between the courteous and professional treatment of Health Care Professionals by ABHI members, with the desire to avoid even the appearance that hospitality may be used by members as a means to induce Health Care Professionals to purchase, prescribe or recommend company products. Accordingly, members must assess what is 'reasonable' in any given situation and regional variations will apply. As a general guideline, 'reasonable' should be interpreted as the appropriate standard for the given location and must comply with the local laws, regulations and professional codes of conduct. If the meeting venue is a hotel which complies with the requirements of the guidelines, it would be acceptable for members to offer participants meals and accommodation at the same hotel. The term 'hospitality' includes meals and accommodation. It is important that members differentiate between 'hospitality' which is permitted and 'entertainment' which is not. 'Entertainment' includes, but is not limited to, dancing or arrangements where live music is the main attraction, sight-seeing trips, theatre excursions, sporting events and other leisure arrangements.

Q9. Under the guidelines, what standard of air travel may a member provide a Health Care Professional attending member-sponsored training?

A9. Members may provide only economy or standard class air travel to Health Care Professionals unless the flight time is of a duration of greater than 5 hours; in which case, it is appropriate to consider premium economy or business class provided this is permitted under the national and local laws, regulations and professional codes of conduct of the country where the Health Care Professional is licensed to practise.

Q10. What does the term 'facilitate' mean where used in connection with the guest or spouse expenses?

A10. The term 'facilitate' refers to the prior arrangement, organisation or booking of meals, travel or accommodation by a member on behalf of the spouse/guest of a Health Care Professional participant. Such organisation or booking is not permitted unless the individual qualifies as a participant in their own right. If Health Care Professionals attending product training wish to be accompanied by a spouse/guest who does not have a professional interest in the information being shared, the Health Care Professional must take sole responsibility for the payment and organisation of the spouse/guest's expenses.

Q11. In the event that a Health Care Professional is accompanied by a spouse/guest at member-sponsored product training, may the spouse/guest be admitted to any member-related activity?

A11. It would not be appropriate for the spouse/guest of a Health Care Professional to be invited to attend any of the member-related activities, including associated meals even when the Health Care Professional has paid for the spouse/guest expenses. Any uninvited appearance by a spouse/guest should be strongly discouraged.

Q12. In connection with providing financial support to cover the cost of conference attendance by individual Health Care Professionals, what are deemed to be reasonable travel, meals and accommodation?

A12. Members must assess what is reasonable in any given location and regional and country variations will apply. However, as with member-sponsored training, the hospitality provided by members at third party educational events should not be of such a level as to become the main attraction of the event. Accordingly, hotel accommodation should not normally be provided at top category or luxury hotels, air travel should be economy or standard class unless the duration of the flight extends beyond 5 hours (in which case premium economy or business class may be considered) and meals should be of a standard that Health Care Professionals would routinely expect if they were paying for them out of their own pockets. A meal at the conference hotel with wine would normally be considered acceptable.

Q13. Is it appropriate for members to cover the full registration fee of third-party conferences where such fee covers the cost of a conference dinner and/or social or cultural activities?

A13. Members must not pay for the expenses which relate to the purely social or cultural aspects of the conference. Modest and incidental gatherings such as the welcome cocktail are appropriate and members may cover these expenses. Where the registration fee includes an element of entertainment members must request that these elements are separated in the registration fee and subsequently not pay for this element. If the conference organiser is unable to separate the entertainment costs from the registration fee, members should assess the image that may be projected to the public and reconsider supporting the event. For the avoidance of doubt, the conference dinner may be supported if it is expected that all delegates to the conference would normally attend and provided the dinner is otherwise in line with the requirements of the guidelines.

Q14. Are members permitted to invite Health Care Professionals to educational conferences, offering to cover their reasonable expenses or are members only permitted to support Health Care Professional attendance at conferences in response to unsolicited requests from Health Care Professionals?

A14. Members are permitted to invite Health Care Professionals to attend educational conferences provided the selection is based upon the training and educational requirements of the individual Health Care Professional and is in no way tied to the Health Care Professional's past or potential future use of the member's products or services.

Q15. How does the Code apply where a member organises or sponsors an international meeting with Health Care Professionals attending from various European countries?

A15. When organising or sponsoring international events, members must comply with the regulations on hospitality applicable to each Health Care Professional in their respective countries and with the regulations in the country where the event takes place. Each Health Care Professional remains subject to the regulations of his/her own country, irrespective of where the event takes place. In the case of conflict, the member is recommended to apply the stricter rule.

Q16. Is it acceptable to offer a cash advance by way of a cheque or bank transfer payable to a Health Care Professional for a specific amount to cover all or part of the Health Care Professional's travel or accommodation expenses for attendance at a conference?

A16. It is not acceptable to make an advance payment to a Health Care Professional to cover prospective expenses. Payments should generally be made to the supplier/vendor or intermediary agency. Alternatively, members may reimburse individual Health Care Professional expenses retrospectively against original invoices or receipts.

Q17. May member companies offer to cover the travel and accommodation expenses of Health Care Professionals for periods that extend beyond the duration of the congress or other training programme attended?

A17. Generally, travel and accommodation support given by member companies to Health Care Professionals should be strictly tailored to the duration of the congress or educational event. However, where the travel expenses incurred are significantly reduced by the Health Care Professional travelling at alternate times, the travel arrangements may be extended. Any accommodation expenses relating to the extended stay must be met by the Health Care Professional.

Q18. May member companies organise the travel and accommodation arrangements of the spouse or other guest of a Health Care Professional attending a third-party congress if the Health Care Professional pays for the spouse or guest?

A18. No, unless that person qualifies as a proper delegate or participant at the meeting in their own right, it would not be appropriate for a member to organise the travel and/or accommodation arrangements of the spouse or guest of a Health Care Professional, irrespective of who pays. Such actions are open to misinterpretation.

Q19. Is it permissible under the Code for member companies to sponsor the attendance of individual Health Care Professionals on courses of further education?

A19. No, members may not sponsor individual Health Care Professionals to attend courses of further education. Members may make educational grants available and provide such grants to the training institution but must have no role in the selection of the individual who will receive the grant.

Q20. Is it acceptable for members to subsidise or pay for the attendance of Health Care Professionals at events organised by medical device industry associations or by groups of companies (in both cases with or without the involvement of third parties)?

A20. Yes, this is acceptable provided the Health Care Professional is likely to obtain an objective benefit from such attendance and there is no overt commercial promotion. For example, meetings arranged for the purpose of training Health Care Professionals on the guidelines or gaining a better understanding of the industry in general, would be acceptable.

Q21. Is it appropriate for members to invite Health Care Professionals on company plant or factory tours where the Health Care Professionals reside outside the country of location of the plant or factory?

A21. Yes, it is appropriate for members to invite Health Care Professionals to plant or factory tours in countries outside their country of residence if there is a legitimate business purpose and the tour complies with the guidelines in all respects. Accordingly, members should ensure that appropriate documentation is put in place, hotel accommodation is not normally provided at top category or luxury hotels, air travel is economy or standard class unless the duration of the flight extends beyond 5 hours (in which case premium economy or business class may be considered) and meals are of a standard that Health Care Professionals would routinely expect if they were paying for them out of their own pocket.

Q22. What general criteria need to be fulfilled for arrangements with Health Care Professionals that are engaged to provide genuine consultancy services?

A22. The criteria that should be adopted are as follows:

- A legitimate business need is identified in advance.
- The criteria for the selection of Health Care Professionals are related to the identified need.
- A written agreement specifying the services to be provided is in place before the service is rendered.
- Compensation for the service rendered is reasonable and according to fair market value.
- Members document the work products generated by the Health Care Professionals; and the arrangement is entered into without intention of using it as a means to induce the recommendation, purchase, prescription, supply or sale of medical products or services.

Q23. Under the guidelines, is it compulsory that a Health Care Professional engaged as a consultant by a member obtains a written permission from the main health care institution where the Health Care Professional conducts his or her work to render services as a consultant for the member?

A23. Under the guidelines, written permission is not required. However, interaction between industry and Health Care Professionals must be transparent and comply with national and local laws, regulations and professional codes of conduct. In countries where specific provision is not made, members shall nevertheless maintain appropriate transparency by requiring prior written notification is made to the hospital administration or the Health Care Professional's superior (or other locally-designated body), fully disclosing the purpose and scope of the engagement.

Q24. According to the guidelines, would it be permissible for members to organise entertainment or other social or leisure activities in association with meetings with Health Care Professionals who are engaged as consultants by the member?

A24. No. Members should not provide or organise entertainment for Health Care Professionals who are engaged as consultants by the member.

Q25. Is it appropriate for members to cover the cost of meals, travel or other hospitality expenses of the spouse or guest accompanying Health Care Professionals at member-sponsored consultant meetings?

A25. No, it is not appropriate for members to pay for the meals, travel or accommodation of persons accompanying Health Care Professional consultants at member-sponsored consultant meetings. Furthermore, members should not organise the travel or accommodation of such guests.

Q26. When a member contracts with a group of Health Care Professionals for the development of intellectual property, is it appropriate for each Health Care Professional pertaining to that group to receive financial compensation in respect of the co-developed medical devices prescribed or used by the other co-developer Health Care Professionals?

A26. No, it is advisable that the Health Care Professionals who co-develop one or more medical devices under an appropriate contract with a member do not receive financial compensation in respect of the co-developed medical devices used or prescribed by the other co-developer Health Care Professionals.

Q27. Please provide some examples of items of modest value that are 'related to the Health Care Professional's practice or for the benefit of patients'.

A27. Mugs, stationery items, calendars, diaries, computer accessories for business use and clinical items such as wipes, nail brushes, surgical gloves and tourniquets are examples of modest value items that would be appropriate for use as gifts for Health Care Professionals provided their value falls within the maximum value prescribed under national and local laws, regulations and industry and professional codes of conduct. Items which are primarily for use in the home or car are not appropriate as they are not related to the Health Care Professional's practice nor are they for the benefit of patients.

Q28. Are prize draws and competitions appropriate forms of promoting medical devices?

A28. Prize draws and other competitions may be appropriate if the prize awarded complies with the guidelines on gifts and is in accordance with national and local laws, regulations and industry and professional codes of conduct.

Q29. Which items are regarded as cash equivalents?

A29. Items that have a specified cash value such as store vouchers, book tokens, music tokens or vouchers offering a discount or free gift are regarded as cash equivalents.

Q30. May a member provide a small gift to a Health Care Professional upon significant life events such as a marriage, birth, birthday or death?

A30. The guidelines restrict the types of gifts that may be given to a Health Care Professional and it would not be appropriate to give gifts to mark significant life events such as a marriage, birth or birthday. However, in the case of death, it is for each member to determine the appropriateness of making a tasteful gift as a mark of respect.

Q31. May a member give gifts to members of staff of a Health Care Professional who are not themselves Health Care Professionals?

A31. Gifts given to the staff of a Health Care Professional should be treated as though they were given to the Health Care Professional and, accordingly, must comply with the provisions of the guidelines in all respects.

Q32. Can a member make a charitable donation to a non-profit organisation in the name of a Health Care Professional?

A32. No. All contributions made with a member's funds must represent the member as the provider of the donation.

Q33. Can a member buy a stand or booth at a conference organised by a charity?

A33. Yes, but this activity would not be considered to be a charitable donation. It would be considered a legitimate commercial transaction as a normal part of marketing activity.

Q34. Under the guidelines, may a member make a charitable donation such as the purchase of a table of dinner invitations at a fundraising dinner?

A34. Yes, charitable donations made by members may take the form of dinner invitations for a fundraising dinner or participating in other recreational events such as a fundraising golf tournament, if arranged by a charity or other eligible entity. However, the member should not invite Health Care Professionals to attend the event at the member's expense. The member may use some or all of its ticket allotment for its own employees and return any unused portion to the sponsoring organisation for use as the sponsoring organisation sees fit.

Q35. Can a member pay a research grant to a Health Care Professional for a clinical study where the member is named as the sponsor of the study?

A35. No. Clinical investigators participating in a member-sponsored study are regarded as providing a consultancy service and arrangements should follow the section on Arrangements with Consultants in Appendix 1 ABHI Guidelines on Interactions with Health Care Professionals.

Q36. Do the guidelines apply to requests for educational support made by medical institutions and group purchasing bodies in the context of public tender offerings?

A36. No. Such requests and the subsequent financial support made are not considered to be 'educational grants' for the purpose of these guidelines. Such arrangements are commercial in nature and not philanthropic and should be documented in a written commercial agreement in accordance with normal business practice.

ABHI Competition Law Compliance Guidelines

Our trade association brings together suppliers and others involved in the UK medical sector to discuss issues of industry-wide importance. Our members may compete directly with each other as sellers or buyers. We should therefore ensure that we comply fully with UK competition law and any other equivalent provisions.

EU and national competition law contain two basic prohibitions: one prohibiting anti-competitive agreements between two or more undertakings; and the other prohibiting abuses of a single or collective dominant position (which may apply both to unilateral conduct and to agreements involving a dominant party).

EU competition rules apply only where trade between member states is affected to an appreciable extent, but since national competition law applies even in the absence of cross-border effects, we must always comply with the rules even if arrangements involve members from one country only, or cover only one country or region.

Infringement of EU and national competition law can lead to fines, civil liability for damages and in some countries even to criminal liability. It is the responsibility of the association and each of our members individually to ensure compliance with these guidelines. Liability under the competition laws may be strict – a trade association member may be liable for infringement by the rest of the association.

The following guidelines apply to the association, any working group, individual members, and any subgroup within our association, whether they are large or small.

The prohibition of anti-competitive agreements – general

Generally, no ABHI member should ever discuss or be involved in any of the following activities that will infringe the ban on anti-competitive agreements:

- Price-fixing, including the co-ordination of price ranges, discounts or any other element of pricing, and even discussing prices without actively fixing them.
- Market partitioning such as the allocation of customer groups or territories between competitors, or bid rigging.
- Agreements on investment levels or production quotas.
- The exchange of competitively sensitive information, for instance, on business plans, customer relations or ongoing or planned bids.
- Agreed restrictions on trade between EU Member States such as export bans, or prohibitions on sales to parallel traders.
- Joint negotiations, joint selling or (except after legal review) joint buying.
- Any other agreement restricting competition such as, for instance, a collective boycott, any arrangement to avoid direct competition, or joint action to exclude competitors or new entrants.

To be prohibited by competition law, an agreement need not be written down or binding. The same is true of the decision of an association of undertakings. A verbal information exchange or an informal agreement can be an infringement even if it is merely a “gentleman’s agreement”.

Specific rules for ABHI as a trade association

There are three specific areas that require particular attention in the light of the competition rules: our association’s membership rules; the industry-wide standards we may set; and information exchanged at association meetings.

1. Membership rules

We must not use access to our membership in order to reserve unfair competitive advantage to our members. Accordingly:

- Our criteria for membership are precise, objective, and reasonably necessary for the purpose and efficient governance of our association. We must apply them in a non-discriminatory manner. We must never base a decision on grounds of competition.
- Any proposed expulsion or rejection of a membership application should be based on objective criteria and may be referred for legal review. In case of expulsion or rejection we will allow appeal to an independent tribunal.
- Membership or access to information must not be conditional upon a promise not to participate in competing associations (unless this is strictly necessary to ensure the viability of our association, in which case we should seek legal advice).
- Restrictions on members or rules for discipline must be objective and reasonably necessary for the purposes and good governance of our association. Members have the right to be heard in such cases and an appeal to an independent tribunal will be allowed.

2. Industry standards

ABHI or working groups within the association may develop and promote industry standards, codes of practice or standard terms and conditions for agreements. These standards are allowed where they improve the quality of our members' products or services; however, we are not allowed to use them to restrict competition. Accordingly:

- Standards must be related to specified legitimate objectives, and no more detailed or restrictive than reasonably necessary. Standards should not be used to raise barriers to entry to the market or to exclude competitors.
- Specifications for standards should be publicly accessible, also for non-members.
- Compliance should be voluntary (unless required by law). Standards must not prohibit use of competing technologies in compliant products.
- The award of certificates or seals of approval is allowed as long as criteria are objective and legitimate (for instance, based on verifiable quality levels), and applied on a non-discriminatory basis. Fees should be cost-based.
- The use of standard agreements should not be made compulsory, and standard terms and conditions should not attempt to harmonize 'price-related' clauses.
- A 'best practice' code must not be compulsory and must not limit the way in which participants are able to compete.

3. Information exchange

Members must never exchange competitively sensitive information on their own or their competitors' commercial strategy or anything which would be considered a business secret. We should take particular care in discussions with fellow-members who are or who may become competitors both at formal gatherings and at any informal meeting, even in a social context.

Subjects to avoid are:

- Prices and discounts, or price-related contractual terms (although you may discuss Government-imposed prices and reimbursement policies).
- Client relations, ongoing bids or plans to bid for business.
- Business plans or commercial strategy.
- Competitive strengths/weaknesses in particular areas.
- Production planning or output levels.
- Product development or investment in research programs which is not yet widely known.
- Individualized market share data.

Benchmarking is allowed, so long as the entity collecting and processing the data is bound by confidentiality, and the data are not and cannot be linked to specific competitors. Market surveys are allowed, so long as results are presented in statistical form, individual price information is excluded and competitively sensitive information such as market share and export volumes remain anonymous.

It is acceptable to discuss public policy, educational and scientific developments, regulatory matters of general interest (including Government-imposed prices or reimbursement policies), demographic trends, generally acknowledged industry trends, publicly available information

and historical information that have no impact on future business. Members may display or demonstrate new or existing products, but not discuss non-public R&D or production plans.

The prohibition of abuse of a dominant position

Companies that have the economic power to act independently and set prices regardless of customers' or suppliers' demands or competitive pressure have a special duty to not to restrict competition and not to exploit their customers. Dominance is, in essence, the power to over price, which is assumed if a firm accounts for a dominant share of supply or demand (normally 40% or more). In the medical sector, companies have been found dominant in small markets and members should therefore ensure they are aware of products or services as to which they might be found dominant.

Even if individual members may not be dominant, trade association members may be considered collectively dominant in a particular product market if four or fewer of them account for a large share (say, around 80%) of supply and if they have contacts with each other through the trade association. In such an oligopolistic market, parallel behaviour that restricts competition or exploits customers might be found abusive even if there is no evidence of active collusion.

As soon as a dominant undertaking's behavior has an anti-competitive object or effect, without objective justification, it may result in fines and civil liability. There is no need to demonstrate the existence of an agreement or collusion. Examples of possible abuse of dominance include:

- Imposing excessive or discriminatory terms on customers or suppliers.
- Offering below-cost prices with a view to excluding competitors from the market.
- Limiting production or technical development.
- Refusing to supply parallel traders.
- Refusing to supply competitors or customers with products that they need and cannot buy elsewhere, or
- Making supplies of a product a customer needs dependent on the purchase of a product or service that the customer does not want (tying).

What to do if you suspect a breach of these guidelines?

Presence at meetings where anticompetitive conduct is discussed can be enough to infringe the competition rules. Check the agenda, object in advance to impermissible discussion items and stay away if the agenda is not changed. As soon as you become aware of an infringement, contact your legal counsel, express your disagreement and ensure that a record is kept of your disagreement. If you miss an association meeting, check the minutes upon receipt, and warn your legal counsel if these suggest an infringement. If there is a possibility that sensitive matters are discussed, consider having legal counsel present at meetings.

If you are uncertain whether a particular agreement, discussion or information exchange between competitors is allowed, immediately contact your company counsel, who will take appropriate steps.

Dos and Don'ts

DOs

1. Do read the ABHI Competition Law Compliance Guidelines that are outlined in Appendix 3.
2. Do discuss public policy, education, scientific developments, regulatory matters of general interest, general industry trends, non-individualized (statistical) market surveys or benchmarking projects, publicly available information and historical information, but be prepared to terminate the discussion and record your disagreement if anyone mentions any of the subjects listed in the 'Don't' list below.
3. Do inform ABHI if you disagree with any of its decisions and keep a copy for your files of any such correspondence.
4. Do return commercially sensitive information you receive, without keeping copies, and explain in writing that you do not wish to obtain such information.
5. Do inform your company counsel and ABHI of any approaches seeking to exchange non-public information or co-ordinate conduct on the market.
6. Do ask ABHI to have counsel attend meetings if you or your company have any doubts.

DON'Ts

1. Don't reach understandings or agreements or even hold discussions (especially with a competitor) on anything relating to commercially sensitive topics such as prices, credit terms and billing practices, production, inventory, sales, costs, future business plans, bids or matters relating to individual suppliers or customers.
2. Don't attend meetings without written agenda or clear indication of the purpose.
3. Don't attend unscheduled gatherings unless you know that they are for a *bona fide* purpose or purely social gatherings.
4. Don't accept written non-public information or agree to the exchange of oral non-public information with members who market competing products.
5. Don't participate in information exchanges, market surveys, or benchmarking exercises that allow access to individualized competitive information.
6. Don't engage in joint negotiations, joint sales or joint buying without legal advice.
7. Don't exclude competitors or engage in collective boycotts.

Exchanging Data and Information

Any discussions, whether in a formal or informal context including mere information exchanges, can constitute an anti-competitive agreement or practice.

If you are part of an information or benchmarking 'pool' or other market survey, ensure that individual manufacturers are not identifiable from the data, avoid meetings to discuss the results of the information gathering exercise, and allow open and voluntary participation in the exchange.

Exchanging certain types of sensitive information may be more anti-competitive than is the case with other forms of information. Factors that could make for a high risk of infringement of the competition rules are set out in the table below.

High Risk of Infringement	Low Risk of Infringement
Supply/accept/exchange of information with direct or potential competitors	Publication of information; exchange of information with customers or non-competitors
Supply/accept/exchange information on prices and discounts, individual bids, customer relations, costs, investment and general business strategy, production levels	Exchange information on public policy matters, educational and scientific developments, regulatory matters of general interest, demographic trends, generally acknowledged industry trends, publicly available information
Confidential information	Public domain information
Current information	Historic information
Individual company data	Aggregated industry data
Information exchange in an oligopolistic market structure	
Frequent exchanges	Infrequent exchanges
Implied or explicit recommendations or agreements accompanying the exchange	No further discussion of the information exchanged

ABHI Procedure for Resolution of Complaints received under the ABHI Code of Business Practice

1. Compliance with the Code is mandatory for members of ABHI.
2. Non-members of ABHI may voluntarily submit to the Code and its dispute resolution process.
3. Companies shall endeavour to resolve issues directly between themselves, or consider conciliation, rather than pursuing a formal complaint.
4. There shall be a Code of Practice Complaints Panel, comprising healthcare professionals, lay (non-healthcare or non-industry individuals) and the Chief Executive of ABHI or his nominee as an observer.
5. There shall be a Chairman and Vice-Chairman of the Panel, appointed by ABHI in General Meeting. Vacancies arising shall be temporarily filled by appointment by the Chief Executive.
6. The Chairman and the members of the Panel shall be paid a modest honorarium for time spent and reimbursed reasonable travelling expenses.
7. Complaints about non-compliance with the Code shall be made to the Chairman of the Panel. The Chairman may raise own-motion complaints.
8. A member company shall pay a modest administrative fee on lodging a complaint at a rate publicised from time to time.
9. When a complaint is received, the Chairman or Vice-Chairman shall invite the CEO of the respondent company to comment on the complaint within ten working days.

10. Within two working days of the end of the response period, the Chairman shall decide whether there is a *prima facie* case to answer under the Code, taking into account any response received from the respondent. The Chairman shall forthwith notify the complainant and the respondent of the decision, stating brief reasons.

11. If a *prima facie* case has been determined, the Chairman shall convene a suitable group of three members from the Panel, who shall form the Committee that shall determine the case. The Chairman may take advice from the Chief Executive of ABHI on the suitability of any member of the Panel to sit on any individual case. All Committee members shall be fully independent from the companies involved in any matter.

Any party may submit further evidence within 10 working days of notification of the Chairman's decision, which shall be provided to the other party who shall be given 5 working days to respond.

12. The Panel may request assistance from independent experts on any appropriate matter.

13. Where the Panel makes a decision they shall notify it to the parties with written reasons.

14. The Panel may impose such sanctions as may appear appropriate.

15. The potential sanctions shall include reprimand; imposition of a requirement that the offender take steps to conform with the Code: such steps may be specified in whole or in part, and may be subject to time limits; inspection and audit by a third party, at the offender's expense, of the offender's systems for compliance and of the extent of compliance; requiring companies to recover items given in connection with the promotion of products and/or to issue a customer communication regarding future corrective practice; requiring companies to publish or otherwise disseminate corrective or explanatory information or statements; withdrawal of any 'compliance' logo or equivalent industry accreditation or certification scheme; publication of any decisions or sanctions imposed in such manner or media as may be specified; suspension of a company from membership of the Association for such time period as may be specified, and readmission on such terms as may be specified; expulsion of a member from membership of the Association.

16. A respondent who is held to have breached the Code shall pay the costs of the Panel (on a published scale).

17. An Annual Report shall be published on the operation of the Code and of this Procedure including the number and type of complaints and their outcome.

18. This Procedure shall be reviewed when required, and in any event every three years.

19. The Council of ABHI may amend this procedure from time to time in accordance with its rules of procedure.

Association of British Healthcare Industries
111 Westminster Bridge Road
London SE1 7HR

T (020) 7960 4360
F (020) 7960 4361
enquiries@abhi.org.uk*
www.abhi.org.uk

*ABHI staff can be contacted on email using firstname.lastname@abhi.org.uk

A company limited by guarantee. Registered in England No.1469941. Registered office as above.