



Association of British Healthcare Industries

CODE OF BUSINESS

PRACTICE

MARCH 2016

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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 is 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 programmes by issuing written policies and procedures, and in the case of corporate members, by conducting training programmes 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.

APPENDIX 1

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 is 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 giving prior written notification 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 (see Annexes 1, 2 & 3 to Appendix 2 for *pro forma* letters).
- **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, commissionary 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 giving prior written notification of the sponsorship to the hospital administration, the Health Care Professional's superior or other locally designated competent authority (see Annexes 1 & 2 to Appendix 2 for *pro forma* letters).

- **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 giving prior written notification 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 (see Annex 3 to Appendix 2 for *pro forma* letter).
- 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 5 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 5 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.

APPENDIX 2

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

Q1. What is the “ABHI Code of Ethical Business Practice”? *(Added in September 2011)*

A1. “ABHI Code of Ethical Business Practice” comprises all of the following documents:

- The ABHI Guidelines on Interactions with Healthcare Professionals, as amended from time to time;
- The ABHI Guidance Document – Q&A on the Guidelines on Interactions with Healthcare Professionals , as amended from time to time;
- The ABHI Competition Law Compliance Guidelines, as amended from time to time;
- The ABHI Code of Ethical Business Practice: Procedural Framework, as amended from time to time; and
- The opinions and advisory interpretations of the ABHI Complaints Adjudication Panel.

Q2. Does the definition of Healthcare Professional include purchasing professionals employed in the retail sector, such as a purchasing professional employed by a supermarket chain? *(Added in September 2011)*

A2. No, the definition of Healthcare Professional does not include a purchasing professional employed in the retail sector unless that individual purchaser arranges for the purchase of members' medical devices for or on behalf of medical or clinical personnel. For example, if members' medical devices are sold as part of the common merchandise of the retail outlet, interactions between the member and the purchasing professional do not fall under the guidelines. However, where the members' medical devices are sold in a retail pharmacy (even if this is located within a supermarket unit), interactions between the member and the responsible purchasing professional will fall under the guidelines.

Q3. Under the guidelines, is written notification to the Healthcare 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 Healthcare Professional a gift which are otherwise in line with the requirements of the guidelines?

A3. Written notification to the Healthcare Professional's employer (or other locally-designated body) is required whenever a member engages a Healthcare Professional as a consultant or whenever a member makes a financial contribution to the Healthcare 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 Healthcare Professional's practice, do not require notification.

Q4. Are members required to provide additional written notification under the guidelines to the Healthcare Professional's employer (or other locally-designated body) for member/Healthcare Professional interactions in countries where there are compulsory notification systems already in place? *(NEW – April 2012)*

A4. No, only the compulsory notification is required. Additional notification under the Code is not required in countries where specific requirements of law or regulation govern the transparency of

interactions between industry and Healthcare Professionals. The transparency provisions of the Code apply only in countries where there is an absence of local transparency laws and regulations

Q5. When providing written notification to the Healthcare Professional's employer, are members required to provide details of the proposed financial remuneration members will make to the Healthcare Professional in exchange for the services rendered? *(Added in September 2011)*

A5. The written notification must comply with national and local laws, regulations and professional codes of conduct. In countries where specific provision is not made, there is no requirement to notify employers of the amounts involved. Under the guidelines, members must ensure that the level of remuneration is commensurate with the services provided and set at a fair market value. However, the purpose of the employer notification is to provide transparency on the nature of the interaction between the member company and the Healthcare Professional and to enable the employer to raise objections if they perceive a potential conflict or have other issues concerning the interaction.

Q6. Under the guidelines, what is meant by the term “appropriate location”? *(Amended in April 2012 and September 2013)*

A6. An “appropriate location” geographic location in or near a city or town which is a recognised scientific or business centre, suitable for hosting an event, which is conducive to the exchange of ideas and the transmission of knowledge. It should be centrally located when regard is given to the place of origin of the invited participants. It should also provide ease of access (for example, close proximity to airports, train stations and highways) and have a good ground transportation infrastructure. The geographic location selected should not become the main attraction of the event. Members must consider at all times the image and the perception that may be projected to the public by their choice of location. Furthermore, members must take into account the season during which the conference or meeting is held. The selected time of year must not be associated with a tourist season for the selected geographic location.

The appropriateness of the geographic location applies irrespective of who organises the event and members should take the appropriateness of the geographic in to account when making the decision to support an event whether this is by way of sponsoring HCPs, by leasing booth space for company displays or any form of event advertising or support..

For European and international events, ski resorts in the ski season, island resorts, beach resorts and other geographic locations renowned primarily as seasonal vacation or holiday destinations are not appropriate geographic locations during the season in question. Members must not sponsor individual HCPs or faculty to attend conferences, meetings or events at these locations during those seasons.

The appropriateness of a geographic location may be assessed differently for strictly local events attended by local HCPs.

Q7. Under the guidelines (Section III), what is meant by the term “bona fide” conference (“bona fide independent, educational, scientific or policy-making conferences”)? *(Added in September 2011)*

A7. The term “bona fide” conference means any national or international independent educational, scientific, or policy-making conference, congress or meeting organised by a third-party (i.e. non-member of ABHI), which promotes and facilitates the exchange of 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. Such “bona fide” conference will typically have independent scientific accreditation and provide for CME (continued medical education) and/or CPD (Continuing Professional Development) credits. A “bona fide” conference should be organized in such a way as to be conducive to, and perceived to be

conducive to effective exchange and transmission of knowledge. The principles defined under section II of the Guidelines (“Member-Sponsored Product Training and Education”) with respect to appropriateness of location, venue, guest and spouse as well as the clarifications provided by this Q&A and the Advisory Interpretations of the Eucomed Compliance Panel, also apply to conferences addressed under Section III.

Q8. What criteria should a member apply when considering the country location of product training or education?

A8. 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.

Q9. Can a member use a meeting venue outside Europe?

A9. 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.

Q10. Provided that the geographic location is appropriate, are top category, luxury or resort hotels suitable conference venues for third-party or member-organised events attended by sponsored Healthcare Professionals? (Amended in March 2016)

A10. In principle "No", such hotels are not suitable conference venues. However exceptions can be made if all the following criteria are met:

- The conference is a bona fide educational or scientific event.
- The third-party or member organiser’s promotional material does not feature the on-site leisure aspects of the conference venue as a key attraction.
- The event programme fills the working day for the duration of the conference that is, there are no gaps permitting use of the on-site leisure facilities during the conference.
- In no case can delegates be lodged in luxury hotels even if the venue is considered compliant. However when the geographic location involved presents genuine safety and security issues and the hotel selected for the event is the only safe or secure venue in the area, sponsored HCPs may be lodged in the selected venue.

Under no circumstances are considered compliant as either a conference venue or lodging:

- Resort hotels (meaning a hotel which is part of a complex offering significant recreational, amusement or sporting facilities).
- Cruise ships, golf clubs, spas or hotels with on-site casinos or private beach.

Q11. Under the guidelines, what do the terms “reasonable” and “hospitality” mean?

A11. The guidelines seek to find a balance between the courteous and professional treatment of Healthcare Professionals by ABHI members, with the desire to avoid even the appearance that hospitality may be used by members as a means to induce Healthcare 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.

Q12. Under the guidelines, what standard of air travel may a member provide a Healthcare Professional attending member-sponsored training?

A12. Members may provide only economy or standard class air travel to Healthcare 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 Healthcare Professional is licensed to practise.

Q13. What does the term “facilitate” mean where used in connection with the guest or spouse expenses?

A13. 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 Healthcare Professional participant. Such organisation or booking is not permitted unless the individual qualifies as a participant in their own right. If Healthcare 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 Healthcare Professional must take sole responsibility for the payment and organisation of the spouse/guest’s expenses.

Q14. In the event that a Healthcare Professional is accompanied by a spouse or guest [or by any other person who does not have a bona fide professional interest in the information being shared in the below mentioned events]. (“Guest”) at member-sponsored product training or scientific, educational or training sessions which take place during third-party conferences, may this Guest be admitted to any member-related activity or scientific, educational or training sessions which take place during third-party conferences? (Amended September 2013)

A14. It is not appropriate for a Guest of a Healthcare Professional to attend either member-sponsored product training courses or scientific, educational or training sessions which take place during third-party conferences (unless the individual qualifies as a participant in their own right), or is it appropriate, in the interest of maintaining the scientific exchange, for a Guest to participate in related hospitality events during such training or conferences (for example, lunches and coffee breaks) even when the Healthcare Professional pays for the Guest’s expenses.

ABHI members, however, may consider the sponsorship of third-party conferences which offer extra-curricular programmes/activities beyond the scientific, educational or training sessions for Guests of Healthcare Professionals (such as touristic activities and hospitality), provided that such an extra-curricular programme/activity (including attendance of the conference dinner or a cocktail reception) is subject to a separate charge which must not be paid for, or reimbursed, by the ABHI member.

Where imposed under national or local laws or regulations, such as, for example, in Saudi Arabia, members may make an exception to the above and agree that a male Guest of a female Healthcare Professional may be admitted to member-related activity or scientific, educational or training sessions which take place during third party conferences.

- Q15. In connection with providing financial support to cover the cost of conference attendance by individual Healthcare Professionals, what are deemed to be reasonable travel, meals and accommodation?**
- A15.** 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 Healthcare 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.
- Q16. 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?**
- A16.** 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.
- Q17. Please provide examples of the types of third party educational conferences that members may provide financial support to cover the attendance by individual Healthcare Professionals.**
- A17.** Where permitted under national and local laws, members may provide reasonable financial support to cover the cost of attendance (e.g. registration fee, travel, meal and accommodation) by individual Healthcare Professionals at third party scientific events such as medical congresses and symposia, seminars, training courses and therapy-orientated training.
- Q18. May a member provide financial support to cover the cost of conference attendance (including conference registration and reasonable travel, meals and accommodation) to HCPs who are conference faculty members?**
- A18.** Yes, a member may provide financial support to individual HCP who are conference faculty members to cover the cost of the conference attendance. The principles set out in the guideline in Section III relating to the HCP sponsorship shall apply. Payment should generally be made to the conference organiser or the appropriate supplier/vendor or intermediary agency or alternatively members may reimburse the faculty members expenses against original invoices or receipts. Furthermore, in the interest of transparency, the faculty member should declare that he/she is the recipient of such sponsorship from a member company at the time he/she delivers a presentation at the conference.
- Q19. Are members permitted to invite Healthcare Professionals to educational conferences, offering to cover their reasonable expenses or are members only permitted to support Healthcare Professional attendance at conferences in response to unsolicited requests from Healthcare Professionals?**
- A19.** Members are permitted to invite Healthcare Professionals to attend educational conferences provided the selection is based upon the training and educational requirements of the individual Healthcare Professional and is in no way tied to the Healthcare Professional's past or potential

future use of the member's products or services. Members have to ensure that they comply with all national and local laws, regulations or professional codes of conduct with regards to transparency. In countries where specific provision is not made, Members must maintain appropriate transparency by giving prior written notification to the hospital administration, the HCP superior (or other designated competent authority) expressly offering the possibility to comment and/or oppose the invitation or to designate an alternative HCP recipient.

Q20. How does the Code apply where a member organises or sponsors an international meeting with Healthcare Professionals attending from various European countries?

A20. When organising or sponsoring international events, members must comply with the regulations on hospitality applicable to each Healthcare Professional in their respective countries and with the regulations in the country where the event takes place. Each Healthcare 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.

Q21. Is it acceptable to offer a cash advance by way of a cheque or bank transfer payable to a Healthcare Professional for a specific amount to cover all or part of the Healthcare Professionals' travel or accommodation expenses for attendance at a conference?

A21. It is not acceptable to make an advance payment to a Healthcare Professional to cover prospective expenses. Payments should generally be made to the supplier/vendor or intermediary agency. Alternatively members may reimburse individual Healthcare Professional expenses retrospectively against original invoices or receipts.

Q22. May member companies offer to cover the travel and accommodation expenses of Healthcare Professionals for periods that extend beyond the duration of the congress or other training programme attended?

A22. Generally, travel and accommodation support given by member companies to Healthcare 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 Healthcare Professional travelling at alternate times, the travel arrangements may be extended. Any accommodation expenses relating to the extended stay must be met by the Healthcare Professional.

Q23. May member companies organise the travel and accommodation arrangements of the spouse or other guest of a Healthcare Professional attending a third-party congress if the Healthcare Professional pays for the spouse or guest?

A23. 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 Healthcare Professional, irrespective of who pays. Such actions are open to misinterpretation.

Q24. Is it permissible under the Code for member companies to sponsor the attendance of individual Healthcare Professionals on courses of further education, for example, masters degree courses or modules of such courses?

A24. No, members may not sponsor individual Healthcare Professionals to attend courses of further education such as masters degree courses. 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.

Q25. Is it acceptable for members to subsidise or pay for the attendance of Healthcare Professionals at training or educational events organised by medical device industry associations or by professional associations or patient groups (in both cases with or without the involvement of third parties)? *(Updated in September 2011)*

A25. Yes, this is acceptable provided the Healthcare 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 Healthcare Professionals on the guidelines or gaining a better understanding of the industry in general, would be acceptable.

Q26. Is it appropriate for members to invite Healthcare Professionals on company plant or factory tours where the Healthcare Professionals reside outside the country of location of the plant or factory?

A26. Yes, it is appropriate for members to invite Healthcare 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 Healthcare Professionals would routinely expect if they were paying for them out of their own pocket.

Q27. What general criteria need to be fulfilled for arrangements with Healthcare Professionals that are engaged to provide genuine consultancy services?

A27. The criteria that should be adopted are as follows:

- A legitimate business need is identified in advance;
- The criteria for the selection of Healthcare Professionals are related to the identified need;
- A written agreement specifying the services to be provided is in place before the service is rendered;
- The compensation for the service rendered is reasonable and according to fair market value;
- Members document the work products generated by the Healthcare 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.

Q28. Under the guidelines, is it compulsory that a Healthcare Professional engaged as a consultant by a member obtains a written permission from the main Healthcare institution where the Healthcare Professional conducts his or her work to render services as a consultant for the member?

A28. Under the guidelines, written permission is not required. However, interaction between industry and Healthcare 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 giving prior written notification to the hospital administration or the Healthcare Professional's superior (or other locally-designated body), fully disclosing the purpose and scope of the engagement.

- Q29.** According to the guidelines, would it be permissible for members to organise entertainment or other social or leisure activities in association with meetings with Healthcare Professionals who are engaged as consultants by the member?
- A29.** No, members should not provide or organise entertainment for Healthcare Professionals who are engaged as consultants by the member.
- Q30.** Is it appropriate for members to cover the cost of meals, travel or other hospitality expenses of the spouse or guest accompanying Healthcare Professionals at member-sponsored consultant meetings.
- A30.** No, it is not appropriate for members to pay for the meals, travel or accommodation of persons accompanying Healthcare Professional consultants at member-sponsored consultant meetings. Furthermore, members should not organise the travel or accommodation of such guests.
- Q31.** When a member contracts with a group of Healthcare Professionals for the development of intellectual property, is it appropriate for each Healthcare 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 Healthcare Professionals?
- A31.** No, it is advisable that, the Healthcare 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 Healthcare Professionals.
- Q32.** Please provide some examples of items of modest value that are “related to the Healthcare Professional’s practice or for the benefit of patients”.
- A32.** 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 Healthcare 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 Healthcare Professional’s practice nor are they for the benefit of patients.
- Q33.** Are prize draws and competitions appropriate forms of promoting medical devices?
- A33.** 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.
- Q34.** What are regarded as cash equivalents?
- A34.** 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.
- Q35.** May a member provide a small gift to a Healthcare Professional upon significant life events such as a marriage, birth, birthday or death?
- A35.** The guidelines restrict the types of gifts that may be given to a Healthcare 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.

Q36. May a member give gifts to staff of a Healthcare Professional who are not themselves Healthcare Professionals?

A36. Gifts given to the staff of a Healthcare Professional should be treated as though they were given to the Healthcare Professional and accordingly must comply with the provisions of the guidelines in all respects.

Q37. Where Healthcare Professionals engaged by members as consultants or speakers decline a professional fee for their services, would it be appropriate for the member to show its appreciation by giving the Healthcare Professional a small gift such as a bottle of wine or a bouquet of flowers? (Added in September 2011)

A37. No, it would not be acceptable for the member to make such a gift because to do so could be open to misinterpretation. Such gifts would not comply with Section V of the guidelines in that they do not relate to a Healthcare Professional's practice nor do they serve an educational function.

Q38. Can a member make a charitable donation to a non-profit organisation in the name of a Healthcare Professional?

A38. No, all contributions made with a member's funds must represent the member as the provider of the donation.

Q39. Can a member buy a stand or booth at a conference organised by a charity?

A39. 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 but members should consider the appropriateness of the location and the general circumstances of the event from the perspective of maintaining the reputation of industry.

Q40. Under the guidelines, may a member make a charitable donation such as the purchase of a table of dinner invitations at a fundraising dinner?

A40. 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 Healthcare 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. Furthermore, the member is not permitted to suggest to the sponsoring organisation, the names of Healthcare Professionals who could be invited to attend the event, irrespective of whether or not the specified Healthcare Professionals will be seated at the member's table.

Q41. Is it permissible for a member to make a donation to a Healthcare Professional's designated charity in instances where the Healthcare Professional has requested the member to do so in lieu of receiving a professional fee for the provision of consultancy or speaking services to the member? (Added in September 2011)

A41. No, it would not be appropriate for the member to agree to such a request. Charitable donations to an organisation shall not be made in response to requests from Healthcare Professionals irrespective of the underlying reasons.

Q42. Can a member pay a research grant to a Healthcare Professional for a clinical study where the member is named as the sponsor of the study?

A42. No, clinical investigators participating in a member-sponsored study are regarded as providing a consultancy service and arrangements should follow Section V Arrangements with Consultants.

Q43. Under the guidelines, may members make educational grants to appropriate institutions to cover the cost of books or other educational materials or make a contribution to cover a proportion of a tuition fee? *(Added in September 2011)*

A43. Yes, members may provide educational grants to organisations or entities entitled to receive them for the purpose of purchasing educational materials. Members may also provide support for modules of a course or other components of the total cost of tuition under an educational grant. However, a Member shall not designate or recommend the HCP(s) who will use the materials or attend courses.

Q44. Do the guidelines apply to requests for educational support made by medical institutions and group purchasing bodies in the context of public tender offerings.

A44. 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.

Q45. How is ABHI’s Code of Ethical Business Practice to be applied to collection of post-market data? *(Added April 2012)*

A45. Any and all collection of data must comply with the guidelines. Particular care is required where data is collected on a voluntary basis - such as through clinical registries after a product has been placed on the market (i.e. other than clinical trials or post-market data collection which are required by national law and/or regulatory agencies).

The most important consideration for post-market data collection is that they are performed for **exclusively legitimate purposes**. Examples of legitimate purposes include medical need, including patient safety; research & development; scientific purposes (e.g. performance indicators, comparing objective scientific parameters); regulatory, including post-market surveillance (PMS) and post-market clinical follow up (PMCF), vigilance, safety, or reimbursement and health economic, including clinical and cost-effectiveness and outcomes data relevant to health technology assessments (HTA) and reimbursement decision-making.

Members may not provide **improper inducement** of any participants. The choice of participating Healthcare Professionals should therefore be driven by clinical or medical functions, and not by sales and marketing teams. Members must be vigilant to avoid even the perception that participation in data collection is contingent upon past, present or potential future use of the member's products or services.

As with all interactions with Healthcare Professionals, the four **principles** in the Preamble of the guidelines apply and therefore, in addition to the principle of separation already mentioned in the previous paragraph:

- (a) any remuneration paid must represent a fair market value of the services performed;
- (b) the purpose and scope of the data collection must be transparent and fully disclosed to the appropriate individuals/institutions;
- (c) all elements of the data collection must be documented (including but not limited to the written agreement with the appropriate institution conducting the data collection, setting out, inter alia, the purpose of the data collection, careful and complete records of services actually performed, patient consent forms (where required)).

More generally, members must ensure that collection of data complies with all relevant national and local laws and regulations, including participants’ own professional codes of conduct, and the involvement (if required) of Ethics



Committees. In addition, Medical Device, Data Protection and Tax rules, and the **Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects** must be complied with (and therefore members should obtain, where required, **prior written patient consent**).



ANNEX 1

Notification letter to HCP's Superior re. support for HCP's attendance at Conference

Dear [Name],

[Name + Date + Place of Conference]
[Details of HCP]

It is the current intention of [member company] to offer sponsorship to [details of HCP] to attend the [Name, Date & Place of Conference].

The main scientific topics within the programme are as follows:

- [list scientific topics]
-

The above information, and further details for the Conference can be found at their website, [link to conference website].

It is proposed that the Sponsorship for [HCP] to attend this meeting will cover [insert class of travel] return flights for one person from [Country], registration for the meeting and hotel accommodation for one person on a bed and breakfast basis. [HCP] will be responsible for any additional expenses.

The proposed Sponsorship is not conditional upon any obligation for [HCP] to use, recommend, promote or purchase products of [member company] (or any of its affiliates) and is not intended to influence [HCP] to do so.

As a member of the Association of British Healthcare Industries, we are required to comply with the ABHI Code of Business Practice (the "Code"). Prior to providing any Sponsorship to [HCP] to attend [Conference], the Code requires us to provide you with notification of the proposed Sponsorship. Please therefore treat this letter as this notification, and provide us with any comments you may have (if any) concerning the proposed Sponsorship at your earliest convenience. In particular, if you oppose the current proposed Sponsorship arrangements, or wish to designate an alternative HCP to attend the Conference in place of [HCP] please let us know immediately.

Yours Sincerely,

[Name]
[Title]
[Contact Information]
[Email address]

ANNEX 2

Notification letter to HCP re. support for HCP's attendance at Conference

Dear [Name],

[Name + Date + Place of Conference]

On behalf of [member company] I am pleased to offer you sponsorship to attend the [Name, Date & Place of Conference].

The main scientific topics within the programme are as follows:

- [list scientific topics]
-

The above information, and further details for the Conference can be found at their website, [link to conference website].

Sponsorship for this meeting will cover [insert class of travel] return flights for one person from [Country], registration for the meeting and hotel accommodation for one person on a bed and breakfast basis. You will be responsible for any additional expenses.

If you wish to have someone accompany you, we will not cover any travel, or other costs related to such participation and we are only responsible for your expenses.

Sponsorship is not conditional upon any obligation for you to use, recommend, promote or purchase products of [member company] (or any of its affiliates) and is not intended to influence you to do so.

[member company] will not be responsible for any injury, death or property damage or other loss, claim or injury you may suffer from your attendance at the Conference.

Please note that, as a member of the Association of British Healthcare Industries, we are required to comply with the ABHI Code of Business Practice (the "Code"). Prior to providing any Sponsorship to you to attend [Conference], the Code requires us to provide your hospital administration, or superior, or other designated competent authority with notification of the proposed Sponsorship, offering them the opportunity to comment on or oppose the proposed Sponsorship arrangements and/or to designate an alternative HCP to attend [Conference] in your place.

Please therefore be aware that we will be sending a letter to your hospital administration, or superior, or other designated competent authority (as appropriate) providing this notification in parallel to this letter. In addition however, if your acceptance of the proposed Sponsorship is subject to professional and/or employment rules requiring approval by professional organizations or your employer, you agree to obtain such approval before accepting the present congress attendance sponsorship.

Similarly, if you currently are or within six months will attain, a position to influence purchasing decisions by a government entity or a health-care-related institution owned or substantially controlled by a government or public body, you also agree to notify the purchase decision-maker of this congress attendance sponsorship.



If you would like to accept the sponsorship, Please send me back the signed reply form.

I look forward to meeting you in [Place of Conference]

Yours Sincerely,

[Name]
[Title]
[Contact Information]
[Email address]

Reply from

I [Name HCP address and further identification]

accept the sponsorship to Name Congress from [member company]

I fully understand and agree with the conditions as stipulated in the sponsorship letter;

Signature -----



ANNEX 3

Notification letter to HCP's Superior re: Consultancy Agreement

Dear [Name]

RE: Proposal to enter into a consulting agreement with [Details of HCP]

It is the current intention of [member company] to enter into a consulting agreement with [HCP] ("the Consultant") under the following scope of works:

[Enter scope of works: i.e. research, training etc]

From [start date] to [end date]

The proposed consulting agreement is not conditional upon any obligation for the Consultant to use, recommend, promote or purchase products of [member company] (or any of its affiliates) and is not intended to influence the Consultant to do so.

As a member of the Association of British Healthcare Industries, we are required to comply with the ABHI Code of Business Practice (the "Code"). Prior to entering into any consultancy agreement with the Consultant, the Code requires us to provide you with notification of the proposed agreement. Please therefore treat this letter as this notification, and provide us with any comments you may have (if any) at your earliest convenience. In particular, if you oppose the proposed consultancy agreement, please let us know immediately.

Yours sincerely

[Name]

[Title]

[Contact information]

[Email address]

APPENDIX 3

ABHI Guidelines on Advertisements and Promotions addressed solely or primarily to Healthcare Professionals

A. Introduction & Definitions

1.1 Introduction

These Guidelines and the associated Questions & Answers are published by ABHI because under current UK law and other advertising codes it is difficult to take legal action or to complain against a person or company who publishes misleading promotional material directed solely or primarily at Healthcare Professionals.

Consumer advertising is governed both by legislation (the main legal instruments being listed in Annex 1) and by the codes of advertising practice issued by the Committee of Advertising Practice and the Broadcast Committee of Advertising Practice and administered by the Advertising Standards Association. However, Advertising directed at Healthcare Professionals is not clearly caught by these provisions.

The intention of these Guidelines is to set out principles to be applied to Advertising directed solely or primarily at Healthcare Professionals. These principles will be part of the ABHI Code of Business Practice with which all ABHI Members agree to comply. The principles apply to all such Advertising issued by or on behalf of ABHI Members where it is directed at Healthcare Professionals in the UK. The principles set out in these Guidelines are, however, based upon the general principles contained in existing laws and codes of practice and are therefore generally applicable to all medical devices advertising. ABHI therefore encourages all persons advertising medical devices, not just ABHI Members, to ensure that Advertising published by them or on their behalf complies with these Guidelines.

Complaints that any ABHI Member has failed to comply with these Guidelines will be handled in accordance with the established Complaints Procedure set out in the ABHI Code of Business Practice Complaints Procedure and Panel Constitution, as amended from time to time.

1.2 Definitions

ABHI: Association of British Healthcare Industries

Advertiser: the ABHI Member by or on behalf of whom an Advertisement is placed and/or the ABHI Member supplying the relevant product or Related Service if he has approved the Advertisement or the Advertisement has been approved or placed by the Member's affiliated company which is not a Member of ABHI.

The ABHI Member shall be treated as the Advertiser where the ABHI Member, or the Member's affiliated company which is not a Member of ABHI, has approved Advertisements placed by a third party distributor or other service provider.

Advertisement or Advertising: any marketing communication or Advertorial issued by or on behalf of an Advertiser in whatever form (including but not limited to verbal communications) and through whatever media (including the world wide web) that is intended wholly or mainly to influence Healthcare Professionals or Health Institutions directly or indirectly in (i) their choice of medical devices (or Related Services) to be purchased, leased, used or supplied for use by, or in connection with the treatment of, human patients or in (ii) any recommendation that they make to others about such purchase, lease, use or supply.

An example of Advertising intended to influence Healthcare Professionals or Health Institutions indirectly would be information provided by or on behalf of an Advertiser to journalists working for publications which are directed primarily at Healthcare Professionals or Health Institutions.

For the avoidance of doubt product labelling, packaging and instructions for use shall not in the ordinary course be treated as Advertising for the purpose of these Guidelines.

Advertorial: any communication, feature, announcement or promotion in a form that resembles independent editorial comment published by or on behalf of an ABHI Member, the content of which is controlled by the Advertiser, not the publisher, irrespective whether it is disseminated in return for a payment or other reciprocal arrangement, or free of charge.

CoBP or Code: the code of business practice published by ABHI as amended from time to time.

Guidelines: the ABHI Guidelines on Advertisements and Promotions that are addressed solely or primarily to Healthcare Professionals, as amended from time to time.

Healthcare Professional: includes

- (i) medically qualified personnel including doctors, physicians, psychiatrists, surgeons, dentists, nurses and other personnel authorised to treat human patients (“medical personnel”); and
- (ii) clinical or non-clinical personnel, including technicians and research co-ordinators who work with or under the direction of such medical personnel (“clinical personnel”);
- (iii) persons qualified and permitted to prescribe devices or Related Services; and
- (iv) persons or entities, including hospitals or group purchasing organisations, that directly or indirectly buy, lease, recommend, use, supply or procure the purchase, lease, recommendation, use or supply of medical devices or Related Services for or on behalf of such medical or clinical personnel.

The intention is to include any person or organisation that procures (or influences others to procure) medical devices or Related Services for use in connection with the treatment of human patients and the phrase “Healthcare Professional” should be interpreted accordingly. Thus, in addition to the persons described above, Healthcare Professional includes pharmacists, pharmacy assistants, optometrists, chiropodists, midwives and other ancillary health workers who are entitled to supply medical device products directly to members of the public. It also includes persons who directly or indirectly determine which medical device (or Related Service) is in any manner acquired or supplied for use by, or in connection with the treatment of, human patients.

However, the definition of Healthcare Professional does not include intermediate suppliers of medical devices, such as wholesalers and distributors and/or non-Healthcare Professional retailing entities or persons in the supply chain.

Health Institution: any institution, organisation body or practice (including general practitioner practices) in which Healthcare Professionals are engaged in treating human patients.

Intended Purpose: the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials (Medical Devices Directive 93/42/EEC).

Medical Device Directives means either or both of Directives 93/42/EEC and 90/385/EEC as the same may from time to time be amended.

Member: a member of ABHI or an organisation that has undertaken to comply with the provisions of the ABHI Code of Business Practice.

Related Service: in relation to a medical device, a related service means an activity necessary to make the device available for use. This may include specialist installation services; repair and maintenance services; or end-of-use services such as specialist disposal of the device.

1.3 Interpretation

The singular includes the plural.

Reference to any “commissioned” article, study or material is a reference to work done at the request or on behalf of an Advertiser, often in return for payment or some reward or other support. It may include the work of a journalist or opinion leader carried out directly or indirectly as a result of such request. However, reports on collected medical device clinical data (including reports on clinical investigations, as the expression is used in the Medical Devices Directives) that are written by or at the direction of the clinical investigator (“investigator-initiated reports”) shall not be considered to be “commissioned” whether or not payments have been made in respect of the investigators’ services or expenses reimbursed or other in-kind support has been provided if they meet the conditions below. Equally, reports on collected medical device clinical data (including clinical investigations, as the expression is used in the Medical Devices Directives) that are written by or at the direction of the Advertiser pursuant to an agreement to conduct the clinical data collection (“Advertiser-initiated reports”) shall not be regarded as “commissioned”, always provided that such investigator-initiated or Advertiser-initiated reports relate to clinical data collection and evaluation processes which are:

- a) performed according to scientifically valid standards;
- b) subjected to ethical review independent of the Advertiser, e.g. hospital ethics committee; and
- c) initiated and conducted for scientifically and/or medically legitimate purposes.

B. Guidelines

1. Scope of Guidelines

1.1 These Guidelines apply to all Advertisements produced by or on behalf of Advertisers.

Advertising directed wholly or mainly at consumers, patients or others who are not Healthcare Professionals is not covered by these Guidelines. However, such advertising is subject to general UK advertising law as well as to the industry regulatory codes administered by the Advertising Standards Authority, and it should consequently comply with the law and with those rules.

ABHI and its Members encourage all persons advertising medical devices, not just ABHI Members, to ensure that advertising directed at non-Healthcare Professionals which is published by them or on their behalf complies with these Guidelines.

1.2 The following is a non-exhaustive list of the forms of Advertising that may be captured by these Guidelines:

- Advertisements in Healthcare Professional journals, brochures, leaflets, circulars, mailings, e-mails, text transmissions (including SMS and MMS), social media sites, fax transmissions, catalogues, follow-up literature and other electronic or printed material and/or verbal communications;
- detail aids and other printed material used by representatives;
- posters and other promotional media in public places at Healthcare Professional events, including moving images;
- video and DVD Advertisements intended solely or primarily for release or use at Healthcare Professional events;
- audio-cassettes, films, records, tapes, video recordings intended solely or primarily for release or use at Healthcare Professional events;
- Advertisements in non-broadcast electronic media, including but not limited to: online Advertisements (including banner or pop-up Advertisements and online video Advertisements); search listings; commercial classified Advertisements;
- Advertisements transmitted by Bluetooth; Advertisements distributed through web widgets and online sales promotions and prize promotions
- web-based data services;
- Advertisements in marketing databases containing Healthcare Professionals' contact information;
- Advertorials.

- 1.3 To comply with these Guidelines, Advertising must also comply with all other applicable laws and regulations. For example, Advertising that is in breach of the requirements of the *Business Protection from Misleading Marketing Regulations 2008* will also be a breach of these Guidelines and therefore of the ABHI Code.
- 1.4 Advertising must be suitable for the intended audience and must conform to generally acceptable standards of good taste. It should respect the principles of fair competition generally accepted in business.
- 1.5 An Advertisement should be readily recognisable by the intended audience as an Advertisement and its commercial intent must be made clear if that is not obvious from the context.

2. Accuracy and Substantiation of Claims and Information

- 2.1 Information, claims and comparisons included in or as part of any Advertisement must be accurate, balanced, fair, objective and unambiguous and must be based on a fair evaluation of appropriate evidence and reflect that evidence clearly. They must not mislead the intended audience either directly or by implication, by distortion, exaggeration or undue emphasis. All reasonable efforts must be used to ensure that the substantiation for all information, claims and/or comparisons in an Advertisement is in accordance with an up to date evaluation of all the relevant clinical and scientific evidence.

Material used in or as part of any Advertisement must be sufficiently complete to enable the intended audience to form their own opinion of the therapeutic value of the device.

- 2.2 Different types of evidence are permissible to support claims in Advertisements. The evidence may include clinical data (which could be pre- or post-market data, including registry data); the results of a clinical investigation; laboratory data and testing, including in vitro test data; engineering data; and historical post-market experience.

All evidence must be relevant, balanced, comprehensive and credible and must in all cases be consistent with any specified device's CE marked Intended Purpose, as must the overall impression created by the Advertisement, including any graphics or artwork. Advertisers must in all cases hold documentary evidence (which includes equivalent recorded evidence, e.g. video) to substantiate all claims (direct or implied). This documentary evidence must be in existence before or at the time of the publication of the Advertisement.

- 2.3 Claims or comparisons made, or information included, in Advertisements must accurately reflect the balance of all relevant evidence. If justification for the content of an Advertisement relies on any selection from the available evidence, that selection must be fair and balanced so that the Advertisement does not mislead or give a false impression.

Evidence should be scientifically robust. If there is a significant division of scientific, medical or other expert opinion about any claims made in an Advertisement, those claims must not be presented as being generally agreed and it should be clear from the Advertisement that there is a division of opinion on the relevant matter.

Advertisers must make clear whether the evidence relied upon to substantiate claims used in an Advertisement is clinical or some other type of evidence or a combination. If the

Advertisement includes claims that rely on a particular clinical investigation, that investigation must have been carried out to a standard equivalent to that required for clinical evaluation of a device under Annex X of Directive 93/42/EEC or Annex 7 of Directive 90/385/EEC, as applicable, as at the date of the Advertisement. Advertisers must not imply that claims are based upon peer-reviewed clinical investigation evidence where this is not the case as this will create a misleading impression.

- 2.4** Testimonial evidence on its own is not sufficient substantiation for objective claims. However, provided the overall effect is not misleading, it may be sufficient to use testimonial evidence to justify subjective claims (for example based upon subjective perception) or opinions. Testimonial evidence must not be misleading and must illustrate typical examples only. (See also section 11.1 below.)
- 2.5** If engineering data or in vitro or other laboratory test data is used to substantiate claims made in Advertisements it must be directly relevant to, and significant for, the product being advertised. Particular care must be taken in extrapolating from such data to avoid any misleading impression as to the significance of the data.
- 2.6** Information and claims about side-effects used in or as part of any Advertisement must reflect available evidence or be capable of substantiation by clinical experience. It must not be stated that a product has no side-effects. The word 'safe' must not be used without qualification. Medical devices are all CE marked on a risk-benefit balance. No medical device is 100% safe and advertising claims should not create such an impression i.e. that the medical device is absolutely or completely safe as this is likely to be misleading.
- 2.7** Advertisements must encourage the appropriate use of a device (or Related Service) by presenting it objectively and without exaggerating its properties. Exaggerated or all-embracing claims must not be made, and superlatives must not be used except for those limited circumstances where they relate to a clear fact about a device.

Any claim that a device (or a particular material, component comprised in a device or an active ingredient forming an integral part of that device) has some special merit, quality or property must be substantiated.

- 2.8** The word 'new' must not be used for more than twelve months from the date on which a device or an Intended Purpose of that device or any Related Service has been generally available in the UK in the form referred to in the Advertisement.

The claim that the medical device or Related Service (or new indication or feature) is "new" is no longer acceptable after the device or Related Service (or new indication or feature) has been available for more than a year as this is no longer up-to-date and therefore misleading. While Advertising already in circulation need not be actively withdrawn, Advertisers should not be continuing to use these once the new device or Related Service (or new indication or feature) has been placed on the market in the UK for more than 12 months.

Where a device or Related Service (or new indication or feature) has been available in the UK in only one sector but subsequently becomes available in additional sectors (e.g. private healthcare sector availability is expanded to include NHS availability) it is still not possible to claim the device or Related Service (or new indication or feature) is "new" though it is allowable

to refer to the fact that the device or Related Service (or new indication or feature) is “new to the NHS” provided the overall impression this creates is not misleading.

3. Comparative Advertising

3.1 A comparison used in or as part of any Advertisement is only permitted if:

- it is not misleading;
- devices or services for the same needs or for the same Intended Purpose are compared;
- one or more material, relevant, substantiable and representative features are compared;
- no confusion is created between the device or service advertised and that of a competitor or between the Advertiser’s trade marks, trade names, other distinguishing marks and those of a competitor;
- the trade marks, trade names, other distinguishing marks, products, services, activities or circumstances of a competitor are not discredited or denigrated;
- no unfair advantage is taken of the reputation of a trade mark, trade name or other distinguishing marks of a competitor; and
- the Advertiser’s devices or services are not presented as imitations or replicas of goods or services bearing a competitor’s trade mark or trade name.

3.2 Where comparative claims are made there should be clear evidence to support the claim bearing in mind the potential commercial impact of comparative claims. The intent of any comparison should be that it provides valuable, objective and accurate information comparing products and/or associated services for the benefit of Healthcare Professionals and their patients. It should not simply be a means of denigrating a competitor’s product or Related Service.

3.3 Care must be taken not to mislead when expressing data as percentages. Patient numbers should be included whenever possible. Differences which do not reach statistical significance must not be presented in such a way as to mislead.

3.4 It is acceptable for a member to report on the outcomes of comparative testing of medical devices in an Advertisement provided:

- (i) the devices have been subjected to the same and appropriate testing; and
- (ii) the outcomes are reported in a fair and balanced manner; and each outcome is referenced and consistent with the body of evidence.

3.5 It is acceptable to report on the outcomes of separate testing of medical devices in an Advertisement provided a qualifying statement is included to make clear that the substantiating data comes from separate studies.

- 3.6** Hanging comparisons whereby a device or Related Service is described as being better or stronger or such like without stating that with which the device is compared must not be made.

4. Requests for Substantiating Data

- 4.1** If a bona fide request is made to an Advertiser to substantiate any information, claim or comparison used in or as part of any Advertisement, the enquiry must be acknowledged within ten working days of the date when the Advertiser has sufficient information to understand the nature of the enquiry or complaint. The initial response should where relevant indicate when a full response will be provided.

Unless section 4.2 applies, a full response together with relevant substantiating data must be provided within thirty working days of an adequately clear request being received.

A bona fide request means one received from an independent Healthcare Professional or from another person (including from companies) having a legitimate interest in the substantiation requested. However, there is no requirement to respond to fishing expeditions by competitors or others that are simply designed to obtain confidential or commercially sensitive information about the Advertiser's products or business.

There is no need to supply information relating to the validation of a device's explicit CE marked Intended Purpose or for claims that are expressly covered by the Intended Purpose of the device.

- 4.2** In justifying an Advertisement, the Advertiser must be prepared to give relevant technical, clinical and scientific data. The Advertiser may be justified in requiring the person requesting substantiation of the Advertisement to enter into a confidentiality agreement in relation to information disclosed.

An Advertiser shall not be obliged to disclose confidential or commercially sensitive data or material directly to the person requesting it where such disclosure might cause financial harm or otherwise damage the business of the Advertiser. In such cases confidential disclosure to an independent mediator or expert or, (if a formal complaint is to be lodged under the Code) to the Panel, for consideration may be appropriate. Confidential disclosure of this type shall not be appropriate in cases where it is primarily the insufficiency of the Advertiser's substantiating data, which is likely to result in the financial harm or damage to the Advertiser's business.

5. Use of Published Data to Support Advertising

- 5.1** When promotional material used in or as part of any Advertisement refers to published studies, including clinical investigations, clear references must be given.
- 5.2** All artwork used in or as part of any Advertisement including illustrations, graphs and tables must conform to the letter and spirit of these Guidelines and of the CoBP. If artwork or data is taken from published studies a reference must be given. Graphs and tables must be presented in such a way as to give a clear, fair, balanced view of the matters with which they deal, and must not be included unless they are relevant to the claims or comparisons being made.

If a graph or table is reproduced from a published study, it should not be altered unnecessarily. In any event, the way in which the material is used must not distort or give a false impression of

the evidence published in that study and the Advertiser must clearly state that the material has been modified.

- 5.3** Advertisers may use scientific peer-reviewed journals, clinical or otherwise, to substantiate claims made in an Advertisement. There may also be relevant data to be found in publications of patient data and case studies, whether or not it is published in a scientific journal. The key issues are the quality, relevance and overall credibility of the data when relied upon to support claims made in an Advertisement. (See also section 7.1 of these Guidelines).

6. No Disparagement

- 6.1** The products and activities of other medical device companies must not be disparaged in an Advertisement.
- 6.2** Healthcare Professionals and the clinical and scientific opinions of Healthcare Professionals must not be disparaged in any Advertisement.

7. Non-Refereed Articles

- 7.1** Journal or other articles which have not been refereed are unlikely to be sufficiently robust to justify science-based claims about a device's safety or performance on their own. It also follows that reprints of such material must not be provided to Healthcare Professionals unsolicited.

However, if claims in an Advertisement are based upon subjective patient or consumer perceptions, it may be acceptable to use non-refereed articles to promote those specific aspects of a product.

8. Off-Label Use

- 8.1** If Journal articles discuss off-label use of a particular device, such discussion must not be used with the intention of promoting such off-label use. For example, the unsolicited supply of such materials to Healthcare Professionals would be an infringement of these Guidelines. However, it is permissible to supply such articles upon receipt of a bona fide unsolicited, written request from a Healthcare Professional. Care should be taken to record the written request and the response sent.

9. Quotations

- 9.1** Quotations from medical and scientific literature or from personal communications must be accurate and must reflect the meaning of the author. The precise source of the quotation must be identified.
- 9.2** Quotations relating to devices taken from public broadcasts, for example on radio and television, and from private occasions, such as medical conferences or symposia, must not be used without the formal permission of the speaker.
- 9.3** Where references are made to medical and scientific literature or to personal communications these must accurately reflect the author's meaning.

- 9.4 All reasonable care must be taken to avoid ascribing claims or views to authors when these no longer represent the current views of the authors concerned.

10. Material Commissioned by the Advertiser

- 10.1 An article or piece of information that is commissioned by or on behalf of the Advertiser must be clearly identified as such on its face and the Advertiser must also be clearly identified.

In line with section A 1.3 of these Guidelines, “commissioning” of an article in this context means the provision of any financial or other support or reward to the author for the purpose of producing the article. This includes the provision of any in-kind support, e.g. products, facilities, secretarial or administrative support by Advertisers. However, reports on collected medical device clinical data (including reports on clinical investigations, as the expression is used in the Medical Devices Directives) that are written by or at the direction of the clinical investigator (“investigator-initiated reports”) shall not be considered to be “commissioned” whether or not payments have been made in respect of the investigators’ services or expenses reimbursed or other in-kind support has been provided if they meet the conditions below. Equally, reports on collected medical device clinical data (including clinical investigations, as the expression is used in the Medical Devices Directives) that are written by or at the direction of the Advertiser pursuant to an agreement to conduct the clinical data collection (“Advertiser-initiated reports”) shall not be regarded as “commissioned”, always provided that such investigator-initiated or Advertiser-initiated reports relate to clinical data collection and evaluation processes which are:

- a) performed according to scientifically valid standards;
- b) subjected to ethical review independent of the Advertiser, e.g. hospital ethics committee; and
- c) initiated and conducted for scientifically and/or medically legitimate purposes.

- 10.2 Where such a commissioned article is used solely or primarily for the purpose of supporting a claim, including a comparative claim, the article cannot be the sole or primary evidence relied on to substantiate the claim – the claim must also be separately substantiated by other, additional evidence of sufficient quality and quantity to meet the standards specified in these Guidelines. Investigator-initiated or Advertiser-initiated reports which meet the conditions set out at section A 1.3 of these Guidelines may, however, provide independent substantiation for the safety or performance of a device or Related Service.

11. Testimonials and Endorsements

- 11.1 For testimonials and/or endorsements (including but not limited to blogs) to be used in or in support of any Advertisement, the Advertiser must ensure that the testimonials or endorsements (whether from patients, suitably qualified Healthcare Professionals, celebrities or members of the public generally) whether written or spoken, are documented, genuine, not misleading and illustrate typical examples only, except where these are obviously fictitious.

In this context “typical” means something that is experienced by the great majority of patients or users, as applicable. If a testimonial or endorsement refers to a condition or situation experienced by only one or very few patients or users, this must be made clear. Also in this

context “suitably qualified Healthcare Professionals” means persons who can provide suitable credentials evidencing relevant professional expertise or qualifications and accreditation by a professional or regulatory body that has systems for dealing with complaints and taking disciplinary action and has registration based on minimum standards for training and qualifications.

If a testimonial or endorsement which is used in Advertising is presented by a person other than the person originally providing the testimonial / endorsement – for example when presented by an actor or model – the effect must not mislead or otherwise distort the nature of the testimonial or endorsement. For example, Advertisers could include a suitable caption or other notice where an actor speaks the words of the actual provider of the testimonial to make the actual position clear.

Testimonials or endorsements must relate to the product being Advertised.

If a testimonial or endorsement is used in or in support of any Advertisement, the Advertiser must hold signed and dated documentary evidence, including contact details, for the provider of the testimonial or endorsement in question. The Advertiser must also ensure that he has the consent of the person providing the testimonial or endorsement both to use it in connection with Advertising and (if necessary) to disclose it in connection with the substantiation of any claim.

Testimonials or endorsements taken from published articles should be treated in the same way as quotations (Section 9 above) and in accordance with any other relevant provisions in these Guidelines.

12. Reimbursement of Expenses for Providers of Testimonials or Endorsements

12.1 Any payment made to a person providing a testimonial statement or endorsement (or any other in kind benefit or advantage provided) must not be an inducement or reward for giving that statement. Similarly, no testimonial or endorsement (including any blog) by any person should be used in or to support Advertising if the provider of the testimonial or endorsement has been paid directly or indirectly (including via in kind benefits or advantages) on behalf of the Advertiser to endorse the device or Related Service or to provide the testimonial.

Reimbursement of reasonable and proportionate expenses either by or on behalf of an Advertiser, where the expenses have been incurred by an individual or a company providing a testimonial or an endorsement for use in or in support of Advertising, is permitted always provided such reimbursement:

- (i) is limited to out-of-pocket expenses reasonably incurred by the provider of the testimonial or endorsement in connection with its provision (e.g. reasonable travel costs to reach the filming location provided the location chosen and the mode of travel do not themselves constitute an inducement or reward for providing the testimonial / endorsement); and
- (ii) is either paid to a third party travel agent / vendor to organise the travel / accommodation or only reimbursed to the testimonial / endorsement provider against original invoices or receipts; and

- (iii) is kept entirely separate from any payments or other arrangements relating to any background collaboration or sponsorship activities so that the reimbursement is not, and does not appear to be, a payment made in connection with, or as part of a broader scheme of, paid collaboration or sponsorship between the provider of the testimonial / endorsement and the Advertiser (or any person or organisation connected to him); and
- (iv) specifically in the case of Healthcare Professionals, such reimbursement is only paid in circumstances where the reimbursement payment does not in any way amount to a payment (i.e. as an inducement or reward) for the testimonial or endorsement to be provided as a service by the Healthcare Professional (nor does it have the appearance of being such a payment).

12.2 There should be a written agreement (e.g. letter agreement) signed and dated by or on behalf of both the Advertiser and the provider of the testimonial / endorsement setting out which expenses will be reimbursed and the mechanism of reimbursement (as well as also meeting the other requirements stated at sections 11 and 12.1 above). Expenses should only be reimbursed to the testimonial / endorsement provider by or on behalf of the Advertiser against original invoices or receipts.

If the provider of the testimonial / endorsement is a Healthcare Professional, the written agreement must also comply with the requirements of Appendix 1 of the ABHI Code (Arrangements with Consultants).

It is important that any reimbursement of out-of-pocket expenses should not be, or appear to be, a contrived payment for a testimonial or endorsement. No payment is permitted simply to obtain the testimonial / endorsement of a Healthcare Professional or any other person, and the written agreement must make this clear.

13. Effect of Background Collaboration or Sponsorship on Testimonials and Endorsements

13.1 Advertisers may use testimonials or endorsements of a device or a Related Service by patients, celebrities, suitably qualified Healthcare Professionals or members of the public in, or in support of, Advertising where there is background collaboration or sponsorship by or on behalf of the Advertiser only if:

- a) the background collaboration with or sponsorship by the Advertiser of the individual or company providing the testimonial or endorsement is made clear in the Advertisement; and
- b) the testimonial or endorsement meets the requirements for testimonials and endorsements contained in these Guidelines (see Sections 11 and 12).

“Background collaboration or sponsorship” in this context means any relationship or arrangement(s) (including for example consultancy arrangements or any other type of service provision) between the provider of the testimonial or the endorsement and the Advertiser (or its representatives or affiliates) which is not connected with the provision of the testimonial or the endorsement, irrespective of whether such relationship or arrangement involves any payments (or any other in kind benefit or advantage) or not.



Examples of background collaboration or sponsorship could include arrangements for research, participation on advisory boards or product development.

Reports of clinical investigations shall not be regarded as testimonials or endorsements of a product or Related Service. Rather, they may provide independent substantiation for the safety or performance of a device or Related Service.

Statements made of his/her own volition by a Healthcare Professional (including but not limited to off-the-cuff statements) shall not be treated as testimonials or endorsements even if they have been made at an occasion (such as a conference or meeting) where the meeting organizer is directly or indirectly supported by the Advertiser, always provided such support is incidental to the statement made. If the Advertiser subsequently wishes to use such a statement in or in support of Advertising the Advertiser must ensure all the requirements of these Guidelines regarding testimonials or endorsements (see under sections 11 and 12) are met.

13.2 When Advertisers enter into written agreements covering potential background collaboration or sponsorship activities, Advertisers should anticipate the possibility that the party providing the services under the relevant agreement may at some future time provide a testimonial or endorsement in relation to a device or a Related Service. Advertisers should therefore include provisions in such agreements to cover this eventuality (specifically points (i) and (ii) below) in order to ensure that they will be able to meet the requirements in these Guidelines relating to transparency of background collaboration and sponsorship and use of testimonials and endorsements generally. Such agreements should therefore include written agreement by the potential future testimonial / endorsement provider to:

- (i) disclose clearly and conspicuously in any testimonial / endorsement any background collaboration with, or sponsorship by or on behalf of, the Advertiser; and
- (ii) promptly withdraw, or revise and re-publish any testimonial / endorsement at the Advertiser's reasonable request where the request is made on objective grounds of ensuring safety and effective use within the Intended Purpose of the device or Related Service.

Such agreements should be in writing and signed and dated by both the Advertiser and the potential provider of the testimonial / endorsement.

ANNEX 1

General Advertising Law and Codes

The Business Protection from Misleading Marketing Regulations 2008

The Consumer Protection from Unfair Trading Regulations 2008

The UK Code of Non-Broadcast Advertising, Sales Promotion and Direct Marketing (CAP Code)

The UK Code of Broadcast Advertising (BCAP Code)

APPENDIX 4

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 anticompetitive 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 nondiscriminatory 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 nondiscriminatory 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.
- 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.



ANNEX 1

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

APPENDIX 5

ABHI Code of Business Practice Complaints Procedure and Panel Constitution

Introduction

A Code of Business Practice (“Code”) has been adopted by the Association of British Healthcare Industries (“ABHI”) to govern ethical promotion and sales practices in the medical devices industry in the UK (“the Industry”). Compliance with the Code and with this Procedure is mandatory for members of ABHI and companies which (although not members) have agreed to comply with the Code and this Procedure and accept the jurisdiction of the Panel (together “Applicable Companies”). The Code is administered by a panel of independent individuals (“the Panel”) and chaired by an independent barrister (“Chairman”). “Complaints” made under the Code include direct complaints, as well as indirect complaints made to Eucomed and referred to ABHI for adjudication, and may also include issues raised in the media or otherwise that fall within the remit of the Code.

The Panel is not an investigatory body as such. It asks the company whose activities are the subject of a complaint (“respondent”) for a complete response and may ask the parties to a case for further information in order to clarify the issues. The company or individual making the complaint (“complainant”) has the burden of proving their complaint on the balance of probabilities.

Any company wishing to make a complaint against an Applicable Company utilising this Complaints Procedure must initially attempt to reconcile any dispute with that company through conciliation or mediation procedures or mutual settlement first. Any individual wishing to make a complaint against an Applicable Company utilising this Complaints Procedure must initially attempt to resolve the complaint utilising that company’s internal or external whistleblowing and/or dispute resolution procedures. If, in either case, this does not prove possible then complaints are initially considered by the Chairman who will determine, if appropriate in consultation with the complainant and/or respondent, whether there is a case to answer.

Anonymous complaints (where the complainant does not disclose their identity to the Panel or Chairman) may be accepted in exceptional circumstances at the discretion of the Chairman, however the weight to be attached to any evidence may be adversely affected if the source is anonymous, and thus in many instances it will not be possible for such a complaint to proceed.

Confidential complaints (where the complainant does disclose their identity to the Panel or Chairman but requests (whether at the outset or during the course of the complaint) that their identity remains confidential) are not encouraged but may be accepted at the discretion of the Chairman, however the ability of the respondent to properly respond to information or matters put to them and therefore the Panel’s ability to properly adjudicate on any particular complaint may be adversely affected if the identity of the complainant is kept confidential, and therefore in certain instances it will also not be possible for such a complaint to proceed. Confidential complaints will not be accepted from Applicable Companies.

Reports on cases are published by the Panel and are available on request and on the ABHI’s website www.abhi.org.uk.

Complaints about the conduct of any Applicable Company under the Code or the Interactions of Industry with Healthcare Practitioners in general should be submitted to:

Telephone: +44 (0)20 7960 4360, Facsimile: +44 (0)20 7960 4361,
E-mail: complaints@abhi.org.uk.

Structure and Responsibilities

1. The Panel

- 1.1 The Panel is responsible for resolving complaints made under the Code. It may also assist in arranging for conciliation and/or mediation between companies when requested to do so.
- 1.2 The Panel and Chairman report to the ABHI Executive Committee in respect of their activities and the operation and administration of this Complaints Procedure.

2. The Panel – Constitution and Procedure

- 2.1 The members of the Panel and the Chairman and Vice-Chairman shall be appointed yearly by a majority vote of the Annual General Meeting of the ABHI, and shall comprise a cross-section of independent healthcare professionals, Industry representatives, and lay (non-Industry) individuals. The names of the members of the Panel shall be published on the ABHI website.
- 2.2 Each individual Panel appointed to consider any particular complaint shall, so far as possible, comprise of an appropriate cross-section of Panel members and shall be appointed by the Chairman from the wider list of Panel members referred to. Each individual Panel shall comprise of a minimum of the Chairman and three further Panel members and decisions shall be made by majority voting. The Chairman, and in his absence, the Vice-Chairman, acts as Chairman of the Panel and has both an original and a casting vote.
- 2.3 Rulings are made on the basis that a complainant has the burden of proving their complaint on the balance of probabilities.
- 2.4 In advance of their appointment to an individual Panel to consider any particular complaint, all Panel members involved shall sign an agreed form statement of independence confirming that they have no conflict of interest in adjudicating on the particular complaint.
- 2.5 The Panel may obtain expert assistance in any field. Expert advisers who are consulted may be invited to attend a meeting of the Panel, but have no voting rights. Each such expert shall also be required to confirm that they have no conflict of interest in providing expert assistance on any particular case.
- 2.6 Subject to paragraphs 2.7 and 2.8 below, any decision of the Panel shall be final, and there shall be no appeals procedure against any Panel rulings.
- 2.7 At any time during a complaint handling process the Chairman or the Panel shall be entitled to refer questions of interpretation of the Code in writing to the Eucomed Compliance Panel. The Eucomed Compliance Panel may at its discretion either decline to entertain the matter if it is felt that no question of principle is at issue or accept the interpretation referral, and review and provide guidance on the interpretation of the Code.

Where such a request has been made, the Chairman and the Panel shall be obliged to follow and apply any such guidance provided by Eucomed unless so doing would conflict with UK law. For the avoidance of doubt Eucomed shall not rule on the merits or facts of any particular complaint but only on questions of interpretation of the Code.

- 2.8 This Procedure shall not preclude complainants from having recourse to courts or other tribunals to seek resolution of complaints and any complaints made under the Code and this Procedure should not be initiated or should be suspended in case of initiation of formal civil court proceedings with

respect to the same subject matter. Where a governmental or regulatory investigation or criminal proceedings are either initiated or threatened against an Applicable Company with respect to the same subject matter, that company shall notify the Chairman of the same in confidence, who shall then have the discretion whether or not to suspend any relevant proceedings under this Procedure.

- 2.9 For the avoidance of doubt, all companies or individuals that wish to utilise this Complaints Procedure to submit a Complaint, and all Applicable Companies that have agreed to submit to the jurisdiction of the Panel in respect of a Complaint, shall not, save in respect of fraud, fraudulent misrepresentation, manifest error or gross negligence by the Panel (or a member thereof) in arriving at a Panel ruling, commence legal proceedings or any analogous contentious or complaint proceedings against ABHI, the Panel, or any Panel member, in respect of any loss or damage they may suffer as a consequence of any such Panel ruling. **(NEW - September 2013)**

Complaints Procedure

3. Action on Complaints

- 3.1 Prior to lodging a formal complaint against an Applicable Company under this Procedure, any company wishing to make a complaint against an Applicable Company shall first attempt a genuine mediation with that company in an attempt to reach an amicable solution. For complaints between Applicable Companies, such genuine attempt at mediation shall be a pre-condition before a complaint can be made utilising this Procedure and any such complainant shall adduce sufficient evidence to the Panel to prove such genuine attempts at mediation have been made. Any individual wishing to make a complaint against an Applicable Company utilising this Complaints Procedure must initially attempt to resolve the complaint utilising that company's internal or external whistleblowing and/or dispute resolution procedures. If, in either case, no amicable resolution of the complaint can be reached through such means within a reasonable timeframe however, the complainant shall be entitled to pursue the matter further directly via this Procedure.
- 3.2 Any individual or company making a complaint under this Procedure that is not an Applicable Company shall be required (in the case of a company for a minimum of 18 months, and in the case of an individual for the duration of the Procedure) to undertake to abide by the provisions of the Code and of this Procedure as a pre-condition before a complaint can be made utilising this Procedure.
- 3.3 If a complaint is received about a company other than an Applicable Company, such company will be invited to agree to comply with the Code and accept the jurisdiction of the Panel. In the absence of such agreement however, the complaint will not be accepted for adjudication using this Procedure. Notwithstanding the foregoing, where a complaint is brought in respect of activities undertaken or instigated by an Applicable Company's parent or other affiliated company which is not itself an Applicable Company, the Applicable Company will be deemed as the respondent company for the purposes of this Procedure and the complaint will proceed accordingly.
- 3.4 When the Chairman receives information from which it appears that an Applicable Company may have contravened the Code, the Chairman shall undertake an initial review of the complaint and will determine (if appropriate, in consultation with the complainant and/or respondent) whether there is a *prima facie* case to answer.
- 3.5 If, in the view of the Chairman, a complaint does not show that there may have been a *prima facie* breach of the Code, the complainant shall be so advised. If the complainant does not accept that view, the following paragraphs of this Section 3 shall apply.

- 3.6 In the event that the Chairman determines that there is either a *prima facie* case to answer, or (pursuant to paragraph 3.5) the complainant insists that the complaint is referred to the Panel for adjudication, then the Chairman shall write to the managing director or chief executive or equivalent of the Applicable Company against whom the complaint has been made requesting that it provide a complete response to the matters of complaint.
- 3.7 The respondent company shall provide such a response in writing to the Chairman within 10 working days. If no such response is provided by the respondent company within these timescales then, save as otherwise provided in paragraph 7, the Panel shall make its adjudication on the basis of the information provided by the complainant only. Following receipt by the Chairman of the respondent company's response, the case shall be referred to the Panel to determine whether or not there has been a breach of the Code.
- 3.8 To assist companies in ensuring that a complete response is submitted, the Chairman may suggest relevant supporting material to be supplied, although it is the responsibility of the respondent to ensure that a full response is submitted.
- 3.9 In addition, the Chairman may request (whether at the suggestion of the complainant or respondent or at the behest of the Panel) such further clarifications or documents from either the complainant or respondent within such reasonable timescales as he shall deem prudent and necessary to assist the Panel in making its determination.
- 3.10 If the complainant is not an Applicable Company, the Chairman may suggest the paragraphs of the Code to be addressed, however when the complaint is from an Applicable Company, the complaint must be signed or authorised in writing by the company's managing director or chief executive or equivalent and must state those paragraphs of the Code which are alleged to have been breached.
- 3.11 Unless the information is disclosed in the complaint, any complainant other than an Applicable Company will be asked to confirm in writing whether or not they have any commercial, financial or other interest in the matter of complaint or in the company concerned, such as whether the complainant is an employee or ex-employee, a consultant or ex-consultant. Adjudication of a complaint without this written confirmation will not be permitted to proceed. Such interests will be disclosed to the respondent company and will normally be included in the case report.
- 3.12 When an Applicable Company advises the Chairman or Panel that it may have breached the Code, the Chairman shall treat the matter as a complaint if it relates to a potential breach of the Code or if the company fails to take appropriate action to address the matter. The company's response is invited and the procedure set out in this Section 3 shall be followed.
4. **Complaints Arising from Media Criticism**
- 4.1 If it appears to the Chairman from media reports that an Applicable Company may have breached the Code, the Chairman may at his discretion treat such reports as a complaint if it relates to a potential breach of the Code or if the company fails to take appropriate action to address the matter. The company's response is invited and the procedure set out in Section 3 shall be followed.
- 4.2 The author or editor (as applicable) of the relevant media report may be asked if they want to be involved in the case and whether they have any additional information to submit. If the editor or author declines involvement, this is stated in the case report.

4.3 A published letter from which it appears that an Applicable Company may have breached the Code may also at the discretion of the Chairman be treated as a complaint. The procedure set out in Paragraph 4.1 above shall be followed.

5. Panel Rulings

5.1 Where the Panel rules that there is a breach of the Code, the Panel shall advise the complainant and the respondent of such in writing and give their reasons for the decision.

5.2 The respondent company has ten working days to provide a written undertaking that the activity in question (if not already discontinued) will cease forthwith and that all possible steps will be taken to avoid a similar breach of the Code in the future. This undertaking must be signed by the managing director or chief executive or equivalent of the company and must be accompanied by details of the actions taken by the company to implement the undertaking, including dates and timings and training undertaken.

5.3 In extenuating circumstances, an extension in the time allowed in which to respond may be granted at the discretion of the Chairman in accordance with paragraph 7.

5.4 The respondent company must also pay within twenty working days an administrative charge based on the number of matters ruled in breach of the Code, as determined by the Panel.

5.5 Where the Panel rules that there is no breach of the Code, the Panel shall advise the complainant and the respondent of such in writing and give their reasons for the decision. Where the complaint is from an Applicable Company, the complainant must pay within twenty working days an administrative charge based on the number of matters alleged and ruled not to be in breach of the Code.

5.6 In addition to the foregoing, the Panel may impose additional or alternative sanctions on either of the respondent company (in the event of its breach of the Code) or complainant company (in the event of no breach of the Code) as appropriate in respect of any particular complaint. In particular, the Panel may:

- a. Require the relevant company to publish any communication required by the Panel, including but not limited to explanatory information or statements of future intent or policy;
- b. Require the relevant company to cease to use or publish any ABHI 'compliance' logo or equivalent industry accreditation or certification scheme, and withdraw any material containing it;
- c. Issue a formal reprimand;
- d. Recommend to the appropriate committee of ABHI to suspend the offender from membership of ABHI for a specified period and impose conditions on readmission;
- e. Recommend to the appropriate committee of ABHI to expel the offender from ABHI;
- f. Set time-limits for compliance with any sanction imposed or order made by the Panel in addition to those specified in paragraphs 5.1 to 5.5 above;

- g. Order that either party pay the costs of the Panel, in whole or part, having regard to a standard scale published by ABHI and any other matters considered appropriate;
- h. Provide for further sanctions in the event of further breaches of or non-compliance with the Code or any order, sanction or requirement of the Panel (including time limits), with or without the right to make further representations before such further sanctions are to take effect.

6. Case Reports

- 6.1 At the conclusion of any case under the Code, the Panel shall advise the complainant and the respondent of the outcome and a report shall be published summarising the details of the case.
- 6.2 In a case where the complaint was initiated by an individual, other than in those circumstances where an anonymous or confidential complaint is accepted for adjudication, that individual shall be named in the report.
- 6.3 In a case where the complaint was initiated by a company or by an organisation or official body, that company or organisation or official body shall be named in the report. The respondent company and the product(s) concerned will usually be named in the report unless the Chairman in his discretion deems this inappropriate. Any information given must not, however, be such as to identify any individual person within such company, organisation or official body.
- 6.4 Where expert assistance has been obtained by the Panel, the report will include the name and qualifications of the expert concerned.
- 6.5 Where guidance has been sought from Eucomed, the question raised by the Chairman or the Panel and the guidance received from Eucomed shall be included in the report.
- 6.6 Where a company has been required to issue a statement of its corrective actions, the report will reproduce its text and provide details of how the corrective actions statement was disseminated.
- 6.7 A copy of the report on a case is made available to both the complainant and the respondent company prior to publication. Any amendments to the report suggested by these parties are considered by the Chairman, consulting with the other party where appropriate. The Chairman's decision is final.
- 6.8 Full case reports will appear on a specified section of the ABHI website. Access to the relevant section of the relevant ABHI website referring to cases or decisions is unrestricted.

General Provisions

7. Amendments to Time Periods

- 7.1 The Chairman shall, in extenuating circumstances and at his discretion, be entitled to grant any party to this Procedure an extension in time or amend any timescales specified in this Procedure to the extent that to do so would be fair and reasonable in the circumstances.

8. Withdrawal of Complaints

- 8.1 A complaint may be withdrawn by a complainant with the consent of the respondent company up until such time as the respondent company's comments on the complaint have been received by the Chairman, but not thereafter. In either case, the complainant shall pay an appropriate administrative charge.

9. Charges

- 9.1 The administrative charges referred to in Paragraphs 5.4, 5.5 and 8.1 above are determined by the Executive Committee of the ABHI, subject to approval at the Annual General Meeting of the ABHI by a simple majority of those present and voting, and shall be published on the ABHI website.
- 9.2 Administrative charges are payable only by Applicable Companies, and these companies are liable for such charges whether they are members of the ABHI or not.
- 9.3 Where two or more companies are ruled in breach of the Code in relation to a matter involving a joint activity, each company shall be separately liable to pay any administrative charge which is payable.
- 9.4 Failure to pay any of the administrative charges provided for by this paragraph must be reported by the Chairman or the Panel to the ABHI Executive Committee. In such circumstances, the Panel shall be entitled to impose or recommend such further sanctions as it deems appropriate, including (but not limited to) those referred to in paragraph 5.6.

10. Anonymity and Confidentiality

- 10.1 Any complainant or respondent shall be entitled to request that any document or information provided to the Panel or Chairman pursuant to this Procedure is not disclosed further on the grounds of confidentiality, in particular to either the complainant or respondent as the case may be or in any case report. The Chairman shall decide in his discretion whether to grant such request, in particular taking in to account the ability of either the complainant or the respondent to properly respond to information or matters put to them if such documents or information is excluded and therefore the Panel's ability to properly adjudicate on any particular complaint. The Chairman's decision on this issue shall be final.
- 10.2 Anonymous complaints (where the complainant does not disclose their identity to the Panel or Chairman) may be accepted in exceptional circumstances at the discretion of the Chairman, however the weight to be attached to any evidence may be adversely affected if the source is anonymous, and thus in many instances it will not be possible for such a complaint to proceed.
- 10.3 Confidential complaints (where the complainant does disclose their identity to the Panel or Chairman but requests (whether at the outset or during the course of the complaint) that their identity remains confidential) are not encouraged but may be accepted at the discretion of the Chairman, however the ability of the respondent to properly respond to information or matters put to them and therefore the Panel's ability to properly adjudicate on any particular complaint may be adversely affected if the identity of the complainant is kept confidential, and therefore in certain instances it will also not be possible for such a complaint to proceed. Confidential complaints will not be accepted from Applicable Companies.

11. Amendments to the Code of Business Practice and Complaints Procedure

- 11.1 The Code and this Procedure may be amended by a simple majority of those present and voting at an Executive Committee of the ABHI.
- 11.2 The Panel may, in the light of their experience, make recommendations for amendment of the Code and this Procedure.

Association of British Healthcare Industries

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

*ABHI staff can be contacted on e-mail using firstname.lastname@abhi.org.uk
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