ABHI Guidelines on Advertisements & Promotions addressed solely or primarily to Healthcare Professionals
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Guidelines on Advertisements & Promotions addressed solely or primarily to Health Care Professionals

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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)