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Code of Practice

CODE OF PRACTICE OF Barema

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Barema Code of Practice

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Code of Practice

Introduction

Barema (the Association) is the body which represents manufacturers, distributors and providers of medical equipment to healthcare providers in the United Kingdom.

This Code of Practice has been developed to ensure that the highest standards of self-discipline are enshrined in the conduct of Members of the Association. The Code is considered to be highly desirable because Members believe that their commitment to providing high quality, effective products and services brings major benefits to the health of the nation and the country's economy. Members are thus required to operate a Quality Assurance system which complies with the appropriate standards where this is not already a legal requirement.

The free choice of products and services within the market place should be based not only upon the highest possible standards of quality, but also on accurate, fair and objective information. The Code is intended to foster an ethical, orderly, competent and reliable supply network embracing all sections of the industry for the common good.

Adherence to the Code of Practice is an obligation upon Members of the Association and there is a disciplinary procedure to deal with breaches of the Code.

The Code

1. Quality and Regulatory Compliance

Members are committed to the production and supply of high-quality products and services to the healthcare system in the interest of customer and patient safety and wellbeing.

- 1.1 Members must 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 all products and services provided.
- 1.2 Where products are not subject to specific control, those responsible for their manufacture or importation should ensure that they are manufactured and conform to internationally accepted standards and that the products are distributed by a responsible person/organisation.

2. Customer Service

- 2.1 Members should ensure that products offered for sale are supported by adequate stocks and technical information. In addition, they must

satisfy themselves that diagnostic aids, equipment repair facilities and spare parts will be available to support the customers for at least the normal expected life of the product.

- 2.2 Members should not terminate distribution or agency agreements in such a manner as to prejudice the end user. This is particularly relevant to those products involving warranty work or maintenance. In the event of an agency agreement or a distribution agreement ceasing for whatever reason, members should use their best endeavours to make provision to maintain essential supplies and service.

3. Staff and Training

- 3.1 Members are responsible for ensuring that their staff have the ongoing experience, product knowledge and ability necessary to perform their duties properly and effectively. This includes effective and timely response to customers' queries. Barema Training Courses are available to assist in this process.
- 3.2 Members' staff should possess or be given sufficient clinical and/or technical knowledge to be competent to provide information on the products and services they are selling or promoting in an efficient manner. As a minimum, all customer-facing staff of Full and Provisional Member companies should have attained the LSI (Life Science Industry) registration or equivalent training before completion of two years of employment with a Member.

4. Advertising and Promotions, Information and Claims

This section refers to all material directed at Healthcare Professionals, to those engaged in professions supplementary to the sale of medical equipment, and to other persons concerned with the purchasing of professional medical products and services. (See also Appendix 1 - Barema Guidelines on Advertisements and Promotions addressed solely or primarily to Healthcare Professionals).

- 4.1 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. Advertisements should always be clearly recognizable as such.
- 4.2 Methods of advertising, promotion and activities at exhibitions should not bring the Association or its members into disrepute.
- 4.3 All advertising matter should recognize the professional standing of the recipients and should therefore be in good taste as regards both text and illustrations. Suppressed zeros and unusual scales and differences, which do not reach statistical significance, must not be presented in such a way as to mislead.

- 4.4 In the health sector, the main objective of advertising must be to promote the use of a product by providing correct information about it, and make only such claims as can be satisfactorily substantiated. Methods of promotion should never be such as to bring discredit upon, or reduce confidence in, the Association or the dental industry.
- 4.5 References may be given in advertising matter to already published literature (including theses) directly relevant to the use of a product. However, the rights of the copyright owner must be acknowledged and direct quotations or the reproduction of illustrations from published literature must not be included without the consent of the copyright owner of the original article and/or illustrations. Testimonials from members of the healthcare profession or other scientific disciplines must be attributed.
- 4.6 Promotional material should not imitate the devices, copy, slogans or general layout used by others in a way that is likely to mislead or confuse.
- 4.7 Disparagement, direct or implied, of competitive products or services is considered unethical and unacceptable. The names of other manufacturers and competitors and the brand names of their products or services should not be stated except when making exact reference to already published scientific material or the relevant manufacturer's published data.

5. Free Distribution of Products

- 5.1 The amount of free or trial samples given to an individual user should be no more than is adequate to allow the user to appropriately assess the product.

6. Information to Individuals and the General Public

This includes the passing of information regarding products and services by the industry direct to the general public.

- 6.1 When information on professional matters is requested by the public;
- requests for information on products and services may be dealt with by providing factual information concerning the product or service as allowed by law;
 - requests for clinical information should be declined and the enquirer recommended to consult their own healthcare professional.

7. General Conduct

7.1 Trading between Members

Members are required to maintain the highest standards in their dealings with other Members.

7.2 Interactions with Healthcare Professionals

Compliance with applicable laws and adherence to ethical standards are important to the industry's ability to continue to collaborate effectively with Healthcare Professionals and all customers. Such collaboration can take the form of:

- developing new technologies;
- providing training, education, service and support to enable the safe and effective use of new technologies; and
- supporting research, education, and enhancement of professional skills.

To ensure ethical interactions with individuals or entities that purchase, lease, recommend or use members' products or services, members should duly consider the Barema Guidelines on Interactions with Healthcare Professionals (Appendix2).

8. Powers of Investigation

8.1 Qualifying Complaint

Any complaint under the terms of this Code of Practice must be made in writing to: The Association Chair through the Association Secretary.

8.2 Procedure

Any complaint under the terms of this Code of Practice should be dealt with as per the Association's complaints procedure set out in Appendix 4.

9. Unlawful Payments and Practices

9.1 Members should not offer, make, or authorize payment of money or anything of material value, to unlawfully;

- influence the judgment or conduct of any individual, customer, or company;
- win or retain business;
- influence any act or decision of any governmental official, or
- 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.

10. Competition/Antitrust and Procurement Laws

10.1 Members should conduct their business activities in accordance with the requirements of applicable competition and public procurement laws. Prohibited activities may consist of;

- agreements or understandings with competitors to fix prices, allocate customers or territories or restrict sales;
- exchange of pricing or other confidential information with competitors; and
- price discrimination or refusals to sell. Members should duly consider the BDIA's Guidelines on Competition Law.

11. Compliance and Enforcement

11.1 Members should take measures to ensure compliance with the principles of this Code and its appendices by their employees, agents and representatives.

APPENDIX 1

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

(These Guidelines are provided for the guidance of members as part of the Barema Code of Practice and, at all times, applicable laws take precedence).

A Introduction

1.1 Introduction

Consumer advertising is governed both by legislation 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 Barema Code of Practice with which all Barema Members agree to comply. The principles apply to all such advertising issued by or on behalf of Barema 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 products and services advertising. Barema therefore encourages all persons advertising products and services, not just Barema Members, to ensure that advertising published by them or on their behalf complies with these Guidelines.

Complaints that any Barema Member has failed to comply with these Guidelines will be handled in accordance with the established Complaints Procedure set out in the Barema Code of Practice Complaints Procedure. (Appendix 4).

1.2 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 product clinical data 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 product clinical data 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:

- performed according to scientifically valid standards;
 - subjected to ethical review independent of the advertiser, e.g. hospital ethics committee;
- and
- initiated and conducted for scientifically and/or clinically 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.

Barema and its Members encourage all persons advertising products and services, not just Barema 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 An advertisement should be readily recognizable 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, 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) 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 available 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, dental 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 relevant and applicable legislation, as at the date of the publication 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.

For testimonials and/or endorsements to be used in or in support of any advertisement, the advertiser must ensure that the testimonials or endorsements are documented, genuine, not misleading and illustrate typical examples only.

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 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 and in accordance with any other relevant provisions in these Guidelines.

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 The word ‘new’ must not be used for more than twelve months from the date on which a product 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.

Where a product or related service has been available in the UK in only one sector but subsequently becomes available in additional sectors 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, for example, "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 trademarks, trade names, other distinguishing marks and those of a competitor;
- the trademarks, 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;
- any comparative testing refers only to products or services subjected to the same and appropriate testing;
- the outcomes of any comparative testing are reporting in a fair and balanced manner; and each outcome is referenced and consistent with the body of evidence;
- hanging comparisons whereby a device or related service is described as being better or stronger or such like are not made without stating that with which the device is compared.

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. Disparagement, direct or implied, of competitive products or services is considered unethical and unacceptable. The names of other manufacturers and competitors and the brand names of their products or services should not be stated except when making exact reference to already published scientific material or the relevant manufacturer's published data.

3.3 Care must be taken not to mislead when expressing data as percentages. Sample size must be declared.

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. The initial response should where relevant indicate when a full response will be provided.

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.

5. No Disparagement

5.1 The products, services and activities of other companies must not be disparaged in an advertisement. Disparagement, direct or implied, of competitive products or services is considered unethical and unacceptable. The names of other manufacturers and competitors and the brand names of their products or services should not be stated except when making exact reference to already published scientific material or the relevant manufacturer's published data.

5.2 Healthcare Professionals and the clinical and scientific opinions of Healthcare Professionals must not be disparaged in any advertisement

6. Quotations

- 6.1 Quotations from 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.
 - 6.2 Quotations relating to devices taken from private occasions, such as conferences or symposia, must not be used without the formal permission of the speaker.
 - 6.3 Where references are made to scientific literature or to personal communications these must accurately reflect the author's meaning.
 - 6.4 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.
- 7.0 Material Commissioned by the Advertiser**
- 7.1 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.

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 2

Barema Guidelines on Interactions with Healthcare Professionals

(These Guidelines are provided for the guidance of members as part of the Barema Code of Practice and at all times applicable laws take precedence).

1. Preamble

There are many forms of interactions between Barema members and Healthcare Professionals that advance science or improve patient care. Barema members recognize that adherence to ethical standards and compliance with applicable laws is critical to the technology/devices and associated industry's ability to continue its collaboration with Healthcare Professionals. Members must encourage ethical business practices and socially responsible industry conduct related to their interactions with Healthcare Professionals. Members must continue to respect the obligation of Healthcare Professionals to make independent decisions regarding treatment.

These guidelines set out the standards appropriate to various types of relationships with Healthcare 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 Healthcare Professionals who engage in certain activities in those countries.

2. Member-Sponsored Product Training and Education

Where appropriate, members should make product education and training available to Healthcare Professionals to facilitate the safe and effective use of products and services. 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 Healthcare Professional is licensed to practice.

- Members may pay for reasonable travel and accommodation costs incurred by an attending Healthcare Professional. Members are not permitted to facilitate or pay for meals, travel, accommodation or other expenses for spouses or guests of Healthcare Professionals, or for any other person who does not have a professional interest in the information being shared at the meeting.

3. Third Party Supporting Educational Conference

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

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

- **Sponsorship of Healthcare Professionals**

Members may provide financial support to cover the cost of conference attendance by individual Healthcare 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 any relevant employer, hospital administration, the Healthcare Professional's superior or other locally designated competent authority.

- **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 Healthcare Professionals who are 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.

- **Satellite Symposia & Webinars**

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 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 services, or otherwise be based on an institution's past or potential future use of the company's products or services.

4. **Arrangements with Consultants**

Healthcare Professionals may serve as consultants to members, providing meaningful 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 Healthcare Professionals reasonable compensation for performing these services. The following factors support the existence of a consulting arrangement between members and Healthcare 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.

- The compensation paid to Healthcare 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 products or services which the consultants may use for their own practice. 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.
- All consultancy arrangements with Healthcare Professionals must be documented in writing even where the Healthcare 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 Healthcare 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 Healthcare Professional for the development of intellectual property, there must be a written agreement providing compensation at a fair market value.

5. Gifts

Members occasionally may provide inexpensive, branded or non-branded items as gifts to Healthcare 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 Healthcare Professional is licensed to practice. Gifts must relate to the Healthcare 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.

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 an 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.

6. Educational Grants

Members may provide funds to support genuine independent research, advancement of 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 organizations or entities entitled to receive them under applicable national and local laws and regulations and should not be made to individual Healthcare Professionals.

APPENDIX 3

Definitions

Barema: Association of Anaesthetic & Respiratory Device Suppliers

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

The Barema Member shall be treated as the Advertiser where the Barema Member, or the Member's affiliated company which is not a Member of Barema, 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;

- their choice of product or service to be purchased, leased, used or supplied, or
- in 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 a Barema 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.

Claimant: The instigator of the complaint.

Defender: The member complained of.

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

Healthcare Professionals includes:

- Qualified medical doctors, physicians, psychiatrists, surgeons, nurses, registered operating theatre staff and other personnel authorised to treat human patients; and
- clinical or non-clinical personnel, including technicians and research coordinators who work with or under the direction of such healthcare personnel; and
- persons qualified and permitted to prescribe devices or related services; and
- 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 products or services for or on behalf of persons described above.

The intention is to include any person or organisation that procures (or influences others to procure) products and services 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 products and services directly to members of the public. It also includes persons who determine which product or service is in any manner acquired or supplied.

However, the definition of Healthcare Professional does not include intermediate suppliers of products and services, 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 Barema or an organisation that has undertaken to comply with the provisions of the Barema Code of Business Practice.

Peer-reviewed investigation evidence: Investigation evidence that has been subject to evaluation by one or more people of similar competence to the producers of the work.

Barema Competition Law Compliance Guidelines

(These Guidelines do not form part of the Barema Code of Practice and are for guidance only).

Barema brings together suppliers and others involved in the UK healthcare anaesthetic and respiratory 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 Barema 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 the Barema as a trade association

There are three specific areas that require particular attention in the light of the competition rules: the 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.
- 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 the

Association. Members have the right to be heard in such cases and an appeal to an independent tribunal will be allowed.

2. Industry standards

Barema 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 remains 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 or services, 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).

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.

Dos and Don'ts

Dos

1. Ensure you are familiar with the current Barema Competition Law Compliance Guidelines.
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 Barema 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 Barema of any approaches seeking to exchange non-public information or co-ordinate conduct in the market.
6. Do ask Barema 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 agendas 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 or services.
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 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
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 4

Complaint Procedure

1. In the event of a complaint being received in accordance with the Code of Practice, the following procedure will be followed. A copy of this complaints procedure will be made available to the Complainant.
2. Council shall set up a Complaints Panel which shall consist of not less than three members and an Appeal Panel of not less than three members. No one person shall sit on the Complaints Panel and the Appeal Panel in relation to the same complaint or have any conflicts of interest.
3. The Executive Director shall lay any complaint before the Complaints Panel which within twenty eight days shall decide if it merits further investigation.
4. If the Complaints Panel decides that the complaint is justified it will authorise the Secretariat to investigate the matter and if necessary to seek written submissions from the Member and any other parties deemed appropriate. Members shall respond to such requests within twenty eight days.
5. The Complaints Panel will endeavour to negotiate an agreed resolution of the complaint with the Member and any other party concerned. If the matter is resolved a note to that effect will be kept by the Secretariat and sent to the Member and any other relevant party. If the Complaints Panel cannot resolve the complaint then the Secretariat will offer the Member(s) concerned a formal hearing before the Appeal Panel either in person or by written representation.
6. If the Complainant does not accept the offer of an Appeal Panel hearing within fourteen days it will be assumed that he/she is not proceeding with the complaint.
7. If any Defender does not accept the offer of an Appeal Panel hearing within fourteen days, the Appeal Panel may deal with the matter in his/her absence.
8. The Appeal Panel will determine the complaint by dismissing it or by issuing a reprimand or by suspending or expelling the Member or any combination of these. Suspension will entail the withdrawal of membership privileges and the withdrawal of the member's rate for Association exhibitions. The Appeal Panel will give written reasons for its decision and the decision will be communicated in writing to the Complainant and the Defender(s). Appeal against the decision of the Appeal Panel lies to the Council as set out below.
9. If a written hearing is requested the Secretariat will ask the Complainant to submit a written statement of his/her case and the Defender to respond within a time limit. The Appeal Panel may ask for more information from either party before making its determination.
10. If a formal hearing is requested then the procedure will be as follows:

- 10.1 The Appeal Panel will appoint a Chairman who will follow the procedure below but whose decision as to the conduct of the appeal will be final.
 - 10.2 The Complainant may be accompanied by one other person (including a legal representative if required) to present his/her case. The Member will be required to notify the Secretariat in advance if any witnesses are to be called and to present in advance a written summary of evidence.
 - 10.3 The Complainant will present his/her case.
 - 10.4 The Defender may ask questions.
 - 10.5 The Appeal Panel may ask questions of the Complainant.
 - 10.6 The Defender will present his/her case.
 - 10.7 The Complainant may ask questions.
 - 10.8 The Appeal Panel may ask questions.
 - 10.9 The Defender may sum up his/her case.
 - 10.10 The Complainant may sum up his/her case.
11. The Appeal Panel will determine the complaint as in (8) above.
 12. Appeal to the Council may be in writing or by formal hearing. In either case the procedures will be as outlined above. The appeal will be by way of a re-hearing but the decision of the Appeal Panel and its reasons will be made available to the Council. Members of Council who have sat on the Complaints Panel or the Appeal Panel will not sit on any appeal to Council.

The Council may dismiss or uphold the Appeal Panel's decision. If the Council upholds the complaint it may substitute other disciplinary measures (but within the range outlined above) for those imposed by the Appeals Panel. The Council's decision and its reasons shall be final and shall be communicated to the Defender and the Complainant in writing.

