

This document is the **Code of Practice** referred to in Rules 9 and 17 of the Rules of the Sterile Barrier Association Ltd (the 'SBA') and contains rules and guidance for Members on:

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Part 1 Mitigating Competition Law Risk

Background to the law

The Sterile Barrier Association is a trade association for companies that produce barrier materials, sterilisation systems and processing equipment for the medical device industry in Europe and elsewhere. Members may compete directly with each other as sellers or buyers and it is, therefore, essential that members of the SBA fully comply with EU competition law and equivalent national competition laws applicable to them and or to the Association ("Competition Law")."

It is the policy of the Association not to infringe Competition Law nor to assist or enable others to do so. Accordingly Members must not directly or indirectly use the Association to infringe Competition Law.

The European Union rules on competition are laid out by Articles 101 to 109 of the Treaty on the Functioning of the European Union ("TFEU"). They apply only where trade between member states is affected to an appreciable extent, but since similar national competition law applies even in the absence of cross-border effects, SBA members must always comply with the rules even if arrangements involve members from one country only, or cover only one country or region.

Legal Sanctions

- Infringement of EU and national competition law can lead to fines (up to 10% of the worldwide turnover of the undertaking), civil liability for damages, and in some countries even to criminal liability (in the UK, under the Enterprise Act, 2002 it is a criminal offence for an individual to engage dishonestly in cartel activity, individuals found guilty can be imprisoned for up to 5 years).
- Company directors whose companies breach Competition Law may also be subject to competition disqualification orders, which will prevent them from being involved in the management of a company for up to 15 years).
- In addition, such infringement may also lead to a third party claim (where a third party is affected by the infringement) resulting in a court order to stop the infringement and/or a claim in damages.
- It is the responsibility of the SBA and each of its 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. When a fine is imposed on a trade association and the association is not solvent the members are obliged to cover the amount of the fine by extra contributions.
- Competition authorities in all major jurisdictions, including the European Union and the US practice extensive leniency programmes that grant immunity from or reduction of fines and far reaching benefits with regard to private actions (damage claims) for those companies that uncover anticompetitive agreements and/or conduct.

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Article 101 of the TFEU prohibits: 'All agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the common market, and in particular those which:

- a) directly or indirectly fix purchase or selling prices or any other trading conditions.
- b) limit or control production, markets, technical development, or investment.
- c) share markets or sources of supply.
- d) apply dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage.
- e) make the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.'

Article 102 of the TFEU prohibits: 'Any abuse by one or more undertakings of a dominant position within the common market or in a substantial part of it as incompatible with the common market in so far as it may affect trade between Member States'. Such abuse may, in particular, consist of :

- a) directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions;
- b) limiting production, markets or technical development to the prejudice of consumers;
- c) applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage.
- d) making the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.'

An "undertaking" is set out in EU law as any natural or legal person engaged in economic activity regardless of its legal status and the way in which it is financed. It includes, amongst others, companies, firms, businesses, partnerships, individuals acting as sole traders and trade associations.

Anti-competitive agreements, decisions of trade associations and concerted practices

An agreement covers those which are legally enforceable or not, written or oral and includes so-called gentleman's agreements. There does not have to be a physical meeting of the parties for an agreement to be reached: an exchange of letters or telephone calls may suffice. Presence at a meeting during which anticompetitive conduct occurred leads to a shift of the burden of proof from the authorities to the companies. The company has to provide evidence that its representative attended the meeting for other reasons than to participate in anticompetitive conduct or agreements. The company also has to prove that the respective representative actively and explicitly rejected to participate in such conduct. The fact that a party may have played only a limited part in the setting of the agreement, or may not be fully committed to it, or may have participated under pressure from other parties does not mean that it is not party to the agreement.

Decisions of trade associations would include, for example, the constitution or rules of an association or its recommendations or other activities. The key consideration is whether the object or effect of the decision, whatever form it takes, is to influence the conduct or co-ordinate the activities of its members, even if its recommendations are not binding on its members and may not be fully complied with.

Concerted practice may exist where there is informal co-operation without any formal agreement or decision an example would be parallel behaviour as a result of contact between undertakings leading to conditions of competition which do not correspond to normal conditions of the market.

Rules to avoid competition law problems

The following guidelines apply to the Association, any working groups, individual members, or any subgroup within the Sterile Barrier Association, whether they are large or small.

A. General rules for SBA members

Members should never discuss or be involved in any of the following activities:

- 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 or supplier groups or territories between competitors, or bid rigging.
- The exchange of competitively sensitive information, for instance, on business plans, customer relations or ongoing or planned bids.
- Agreed restriction on trade between EU Member States such as export bans, or prohibitions on sales to parallel traders.
- Agreements on investment levels or production quotas.
- Joint negotiations, joint selling joint production or (except after legal review) joint buying.
- Any other agreement restricting competition such as, for instance, a collective boycott, any agreement to avoid direct competition, or joint action to exclude competitors or new entrants.

B. Specific rules for the SBA as a trade association

1. Membership rules.

The SBA must not use access to our membership in order to reserve unfair competitive advantage to our members, this is particularly so where the effect of exclusion from membership is to put the undertaking(s) concerned at a competitive disadvantage. Accordingly:

- Our criteria for membership of the SBA are transparent, proportionate, non-discriminatory and based on objective standards. Decisions as to membership must never be based on the grounds of competition.
- Any proposed expulsion or rejection of a membership application should be based on objective criteria and may be referred to legal review. In case of expulsion or rejection we will allow appeal to an independent tribunal.

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- Membership or access to information must be conditional upon a promise not to participate in competing associations (unless this is strictly necessary to ensure the viability of the 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.

The SBA or working groups within the association may develop and promote industry standards, codes of practise or standard terms and conditions. If this limits the members in the make-up of the products or services that they can offer or if entry barriers were to be significantly raised as a result of adoption of the standard or if the use of common terms and conditions were imposed upon members, the effects on competition could be appreciable. However, an agreement on technical or design standards may lead to an improvement in production by reducing costs or raising quality, or it may promote technical or economic progress by reducing waste and consumers' search costs. Technical standards can also help to promote and protect consumers.

Under paragraph 3 of Article 101, the prohibitions of Article 101 are inapplicable where the agreement, decision or concerted practice "contributes to improving the production or distribution of goods or to promoting technical or economic progress, which allows the consumer a share of the resulting benefit, and which does not:

- a) Impose on the undertakings concerned restrictions, which are not indispensable to the attainment of these objectives;
- b) Afford such undertakings the possibility of eliminating competition in respect of a substantial part of the products in question

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

3. Information exchange.

Competition may not be harmed and may indeed be enhanced by sharing of information for example information publicly available designed to inform the customer, or information on new technologies or market opportunities and the collection and publication of statistics. These are all legitimate functions of trade associations.

However, Members must never exchange competitively sensitive information on their own or their competitors' commercial strategy or anything, which would be considered as 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, costs, terms of trade and rates and dates of change.
- 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 programmes which is not yet widely known;
- Individualised market share data.

The circulation of purely historical information or the collation of price trends is unlikely to have an appreciable effect on competition, particularly if, for example, the exchange forms part of a scheme of inter-business comparison which is intended to spread best practice, or it is collected, aggregated and disseminated by an independent body. However, compilation of general information, for example on general price trends for the industry must not cover (or allow undertakings to divine) confidential information relating to individual undertakings.

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

The Association will endeavour to identify and follow generally recognised industry best practice from time to time to reduce the risk of breach competition laws generally and particularly if and when it commissions market surveys for its membership. Industry best practice may include the methodologies identified in CEFIC Statistics Service publication entitled "Handling Confidential Statistics in Compliance with Competition Laws" and in particular Statistical Rules 1 to 10 inclusive (adopted in 2013).

It is acceptable to discuss public policy, educational and scientific developments, regulatory matters of general interest (including Government-imposed prices or reimbursement policies), and demographic trends, generally acknowledged industry trends, publicly available information and historical information that have no impact on future business. Members may display or demonstrate new or existing products, but not discuss non-public R&D or production plans.

Avoiding Abuses of a Dominant Position

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

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

As soon as a dominant undertaking's behaviour has any 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);
- Restrictive behaviour on aftermarkets (e.g. accessories, spare parts, service);
- Long term exclusivity contracts with customers or suppliers;
- Application of fidelity rebates that as an object or an effect lead to foreclosure of the market.

TABLES SUMMARISING DO'S and DON'TS

Guidelines on participation in SBA meetings

DON'TS	DO'S
<p>Don't reach understandings or agreements or even hold discussions (especially with a competitor) on anything relating to commercially sensitive topics such as prices, discounts and allowances, credit terms and billing practices, production, output levels, inventory, sales, costs, future business plans, bids or matters relating to individual suppliers or customers.</p> <p>Don't attend meetings without written agenda or clear indication of purpose.</p> <p>Don't attend unscheduled gatherings unless you know that they are for a bona fide purpose or purely social gatherings.</p> <p>Don't accept written non-public information or agree to the exchange of oral non-public information with members who market competing products.</p> <p>Don't participate in information exchanges, market surveys, or benchmarking exercises that allow access to individualised competitive information.</p> <p>Don't engage in joint negotiations, joint sales or joint buying or joint research projects without our legal advice.</p> <p>Don't exclude competitors or engage in collective boycotts</p>	<p>Do read the SBA competition Law Compliance guidelines that precede this annex.</p> <p>Do discuss public policy, education, scientific developments, regulatory matters of general interest, general industry trends (other than as listed in the DON'TS column), non-individualised (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.</p> <p>Do insist on written records of every business meeting you attend.</p> <p>Do inform the SBA if you disagree with any of its decisions and keep a copy for your files of any correspondence.</p> <p>Do return commercially sensitive information you receive, without keeping copies, and explain in writing that you do not wish to obtain such information.</p> <p>Do inform your company legal counsel and the SBA of any approaches seeking to exchange non-public information or co-ordinate conduct on the market.</p> <p>Do ask the SBA to have legal counsel attend meetings if you or your company have any doubts.</p>

Exchanging data and information

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

If you are part of an information or benchmarking 'pool' or other market survey, ensure that individual manufacturers are not identifiable from the data, avoid meetings to discuss the results of the information gathering exercise, and allow open and voluntary participation in 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	Anonymous statistics with a significant number of participating companies
Supply/accept/exchange information on prices and discounts, individual bids, customer relations, costs, investment and general business strategy, production levels	Exchange of information on public policy matters, educational and scientific developments, regulatory matters of general interest, demographic trends, generally acknowledged industry trends, publicly available information, public domain information
Confidential information	Historic information
Current information	Aggregated industry data
Individual company data	
Information exchange in an oligopolistic market structure	
Implied or explicit recommendations or agreements accompanying the exchange	

Part 3 - Guidance on what to do and what will happen if you have a Competition Law Concern with the SBA

General Guidance

If you are unsure what to do given any particular set of circumstances we recommend following the principles set out below:

- Do not participate in the circumstances or activities giving rise to your concern;
- Report the matter to the Association's Board of Directors and or the Director General as soon as possible;
- Report the matter to your company's legal counsel and seek their advice.

Questions over Agenda Items or Pre-Meeting Circumstances

If any representative of your company is due to attend an Association organised meeting (whether in the event they are able to attend or not) and you believe that there is an item on the agenda or other material circumstances connected with that meeting which could give rise to a risk of Competition Law being infringed by the Association or by Members of the Association by virtue of attending that meeting, then you should (as expeditiously as possible) notify the Association's Director General or a member of the Association's Board of Directors to raise and explain your concern. You should also contact your company's legal counsel for advice and/or to notify your company legal counsel of the nature of your concern.

The person to whom you gave notice of the concern will, as soon as practicable, notify the rest of the Association's Board of Director's, who will promptly consider the matter raised (on behalf of the Association) and use reasonable endeavours to address the matter as soon as reasonably practicable.

The Association' Board of Director's review of the matter shall have the objective of eliminating any material risk of Competition Law being infringed by the Association or by its Members in respect of the matter raised.

If the matter is addressed in advance of the meeting by the Board of Directors to your satisfaction, then attendance at the scheduled meeting can go ahead without concern.

If the matter is not dealt with to your satisfaction in advance of the meeting, then you should contact your company legal counsel for advice and subject to that advice, the Association's guidance is that no representative from your company should attend the scheduled meeting. For the avoidance of doubt nothing in this guidance removes any right of a member of the Association to attend meetings of the Association.

In Meeting Behaviour

If during participation in a formal Association meeting you believe there to be a behaviour of the participants at the meeting or an exchange of information or some other matter which is being discussed or there is some other activity taking place, which in your opinion (having regard to these guidelines or otherwise) could give rise to a material risk of Competition Law being infringed by the Association or by members of the Association in connection with that meeting then you should immediately raise the concern in the meeting with the Association Director General and/or with the meeting chairman.

If the matter is not then dealt with to your satisfaction, then the chairman of the meeting shall have the right to temporarily adjourn the meeting for the purpose of the chairman and/or any Association Board members and/or the Director General present or available to immediately discuss your concern in camera.

Upon any such adjourned meeting being reconvened the chairman will state whether the meeting will continue and or what if anything it is proposed will be done to allow the meeting to continue and/or to mitigate any perceived or actual risk of Competition Law being infringed.

If you are unable to agree with the proposed course of action or decision reached then you should consult your company legal counsel as soon as possible and subject to any such advice received (and in default of being able to obtain such advice) the Association's guidance is that you should not participate further in the meeting concerned or in any other formal or informal meetings of the Association or with other Association members relevant to the circumstances which gave rise to your concern. For the avoidance of doubt nothing in this guidance removes any right of a member of the Association to attend meetings of the Association.

In the event of an "in meeting" concern being raised, the chairman of the meeting shall, irrespective of any decision taken at the time, raise the matter with the Association's Board of Directors who will consider and decide what further action (if any) may be needed to mitigate the risk of Competition Law being infringed.

Informal Gatherings at SBA Organised Events

If representatives of your company attend informal gatherings at Association organised events and they observe behaviour of the participants or an exchange of information or some other matter being discussed or activity taking place which in their opinion (having regard to these guidelines or otherwise) could give rise to a material risk of Competition Law being infringed by the Association or by members of the Association in connection with that gathering then you should report the concern and circumstances to the Association's Director General or to a member of the Board of Directors of the Association as soon as possible.

If you are not satisfied with any action taken or remain in doubt as to whether there is a Competition Law risk you should take whatever action you feel correct to protect your company's interests for example not participate further in the relevant gathering or if expedient leaving an Association organised conference. For the avoidance of doubt nothing in this guidance removes any right of a member of the Association to attend meetings of the Association.

You should also contact your company legal counsel for advice and/or to notify your company legal counsel of the nature of your concern.

In the event of such a concern being raised the Association's Board of Directors they will urgently consider and decide what further action (if any) may be needed to mitigate the risk of Competition Law being infringed.

Investigation and Action by the Board

The Association's Board of Directors will normally conduct a reasonable investigation into any alleged breach of this Code of Practice as expeditiously as possible and to the extent reasonable given the Association's resources and commitments.

In any of the situations referred to above relating to a possible concern over Competition Law the Association Board will endeavour to record carefully the concern raised and all the circumstances known to it (arising from its investigation) giving rise to the situation concerned and will minute all of its discussions and decisions on the topic which address any such issue raised by a member (these records will be known as "CL Notification Records").

Subject to Competition Law and or the powers of any Court or Competition Law or other regulator who as a matter of any applicable law can compel the Association to disclose the CL Notification Records, the CL Notification Records may be kept confidential by the Association Board at its discretion.

Where an issue has been raised that in the reasonable opinion of the Association Board has given rise or may in future gives rise to a risk of Competition Law infringement by the Association or its members the Association Board may appraise all Association members of the nature of a concern raised and/or that the concern is being investigated

If the outcome of the investigation concludes that there may have been a breach of the Association Code of Practice, the Association Board will determine and be the final arbiter of whether to refer the matter to the membership for its views either at a plenary session if practicable at the event where the concern arose or at a general meeting of the membership convened pursuant to Rule 9.

Furthermore, in the event of an allegation being made or a Board Member witnessing unacceptable behaviour a senior manager of the respective member company(s) shall be notified by the Director General and a report of any investigation and outcome shall be submitted to them by the Director General. This is because a breach may have a consequence on that company.

Part 3 - Standards of Behaviour Expected of Members

Preserving the SBA's name and reputation

Members of the Association should not conduct themselves in a manner which could tarnish the name and reputation of the Association.

Unacceptable behaviour includes disrespect, discourtesy, rudeness, impertinence, impoliteness, and lack of consideration of others or anything which could reasonably be considered to tarnish the name and reputation of the Association in the reasonable opinion of the Board of Directors of the SBA .

Marketing of SBA membership and use of membership symbols

Members may wish to promote their membership and may do so by using the SBA logo on their website, business letter head, business card, exhibition booth and any other public relations activities.

Membership signs and symbols shall not be used as a quality symbol or certification mark nor in any discriminating manner against non-member companies.

Investigating and reporting

The Board of Directors of the SBA will investigate and endeavour to address any reports of unacceptable behaviour at or in relation to SBA organised events by an individual or group of individuals which any member considers to be unacceptable. The Board will do this as expeditiously as possible and to the extent reasonable given the Association's resources and commitments.

If Board members themselves witness unacceptable behaviour, those Board members present will endeavour to deal with the matter immediately and report the matter as soon as possible to the remainder of the Association Board to investigate.

If the outcome of the investigation concludes that there may have been a breach of the Association Code of Practice, the Association Board will determine and be the final arbiter of whether to refer the matter to the membership for its views either at a plenary session (if practicable at the event where the concern arose) or at a general meeting of the membership convened pursuant to Rule 9.

Furthermore, in the event of an allegation being made or a Board Member witnessing unacceptable behaviour a senior manager of the respective member company(s) shall be notified by the Director General and a report of any investigation and outcome shall be submitted to them by the Director General. This is because a breach may have a consequence on that company.