

## EUCOMED

### Competition Law Compliance Guidelines

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

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

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

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

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

#### **A. The prohibition of anti-competitive agreements – general**

Generally, no EUCOMED 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".

## **B. Specific rules for EUCOMED as a trade association**

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

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

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

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

- Standards must be related to specified legitimate objectives, and no more detailed or restrictive than reasonably necessary. Standards should not be used to raise barriers to entry to the market or to exclude competitors.

- Specifications for standards should be publicly accessible, also for non-members.
- Compliance should be voluntary (unless required by law). Standards must not prohibit use of competing technologies in compliant products.
- The award of certificates or seals of approval is allowed as long as criteria are objective and legitimate (for instance, based on verifiable quality levels), and applied on a non-discriminatory basis. Fees should be cost-based.
- The use of standard agreements should not be made compulsory, and standard terms and conditions should not attempt to harmonize “price-related” clauses.
- A "best practice" code must not be compulsory and must not limit the way in which participants are able to compete.

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

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

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

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

### **C. The prohibition of abuse of a dominant position**

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

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

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

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

### **D. 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.**

## Do's and Don'ts

### Guidelines on participation in EUCOMED meetings

#### DON'TS

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

#### DO'S

1. **Do** read the EUCOMED Competition Law Compliance Guidelines that precede this annex.
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 above.
3. **Do** inform EUCOMED 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 EUCOMED of any approaches seeking to exchange non-public information or coordinate conduct on the market.
6. **Do** ask EUCOMED to have counsel attend meetings if you or your company have any doubts.

## **Exchanging Data and Information**

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

If you are part of an information or benchmarking 'pool' or other market survey, ensure that individual manufacturers are not identifiable from the data, avoid meetings to discuss the results of the information gathering exercise, and allow open and voluntary participation in the exchange. Exchanging certain types of sensitive information may be more anti-competitive than is the case with other forms of information. Factors that could make for a high risk of infringement of the competition rules are set out in the table below.

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