
Eucomed Compliance & Competition Law Guidelines

Revised version, Board approved on 12 June 2012

Introduction

Eucomed represents the medical technology industry in Europe. Our mission is to make modern, innovative and reliable medical technology available to more people. Eucomed brings together manufacturers, suppliers as well as other operators within the field of medical technology used in the diagnosis, prevention, treatment and amelioration of disease and disability. Eucomed believes that high quality, cost effective medical technologies and related services can make significant contribution to the safety and well being of patients and the improvement of healthcare systems.

Eucomed's members recognize that compliance with applicable laws and regulations as well as adherence to ethical standards are both an obligation and a critical step to the achievement of the aforementioned goals and can enhance the reputation and success of the medical technology/device industry.

I. General Compliance Guidelines

A. Unlawful Payments and Practices

Members should not directly or indirectly 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.

B. Quality and Regulatory Compliance

Eucomed's members are committed to the production and supply of high quality medical technologies and related services in the interest of patient safety and well-being.

Members should comply with the legal and regulatory requirements of the countries where they do business. These include both regulations specific to medical technologies and general legal requirements applicable to the medical device and other industries.

The following paragraphs are not intended to be an exhaustive list of requirements but they do highlight areas of particular relevance to the medical device industry.

C. Environmental Issues

Members should conduct their business in compliance with all applicable environmental laws and regulations.

D. Advertising and Promotion

Members should ensure that all promotional presentations, including product claims and comparisons, are accurate, balanced, fair, objective and unambiguous. They should be justified by appropriate evidence. Statements should not mislead the intended audience.

E. Data Privacy

Members should ensure that patient data and other types of confidential or personal data be maintained and used in accordance with applicable legal requirements.

F. Export Controls and Sanctions

Members should ensure compliance with applicable export control laws and other rules restricting trade with certain countries.

II. Competition Law Guidelines

Companies, members of Eucomed, commit to individually determine their behaviour on the market. Both Eucomed and its members agree to comply fully with EU competition law and equivalent provisions of national competition laws, in the EU and outside the territory of the EU.

EU and national competition law contain two basic prohibitions:

1. Prohibiting anti-competitive agreements between two or more undertakings;
2. 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, Eucomed and its members commit to 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 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.

The following Guidelines apply to the organisation, including all working groups, individual members, and any sub-group within the association, irrespective of size and name.

A. The prohibition of anti-competitive agreements – general

As a matter of principle, no Eucomed member should ever discuss or be involved in any of the following activities:

- **Price-fixing**, but also, and not limited to, the coordination of other pricing elements, including discounts, bonuses, surcharges, accounting procedures or profit margins. Discussions on prices are also prohibited;
- **Market partitioning** such as the allocation of customer groups or territories between competitors, as well as bid rigging agreements that involve for example the exchange of prices before or during the tendering procedure or the submission of an artificially high bid;

- **Output restrictions**, such as agreements on investment levels, production quotas or agreed restrictions on trade between EU Member States such as export bans, or prohibitions on sales to parallel traders;
- **Exchange of competitively sensitive information**, for instance, on pricing elements, business plans, customer relations or ongoing or planned bids;
- **Any other agreement restricting competition** such as, for instance, a collective boycott, joint negotiations, (except after legal review) joint selling or joint buying, any arrangement to avoid direct competition, resale price maintenance, pricing policies designed to isolate national markets or joint action to exclude competitors or new entrants.

To be prohibited by competition law, an agreement or a decision of an association of undertakings need not to be written or binding. A verbal information exchange or an informal agreement can be an infringement even if it is merely a "gentleman's agreement". On the other hand, an agreement does not need to be exercised in order to infringe competition law. The potential anti-competitive effect is sufficient.

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:

1 Membership rules. Eucomed must not use access to its membership in order to reserve unfair competitive advantage to its members. Accordingly, membership requirements shall comply with the following rules:

- Membership is voluntary. Companies should not be compelled to join in order to be able to enter the market or trade with Eucomed members.
- Membership is open to any interested party in the industry, based on criteria which are precise, objective, transparent, proportionate and reasonably necessary for the purpose and efficient governance of Eucomed. These criteria are applied in a non-discriminatory manner.
- 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, the Board of Directors of Eucomed, in the presence of the Eucomed (internal or external) legal counsel, shall hear and determine appeals from any decision to admit, expulse or refuse membership by the General Assembly.

- 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 Eucomed, in which case outside legal advice shall be sought).
- Restrictions on members or rules for discipline must be objective and reasonably necessary for the purposes and good governance of our association.

2 Industry standards. Eucomed or the 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, neither Eucomed nor its members are 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.
- 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.
- An ethical or/and "best practice" code must not limit the way in which participants are able to compete, to the extent that the code provisions do govern the parameters that significantly affect of competition between the members (in particular price levels, payment terms, warranty terms or market entry conditions)¹.

¹ Eucomed sought advice from Arnold & Porter (13 May 2011) with regards to the Eucomed Code of Ethical Business Practice. The Memorandum in particular refers to a decision from April 1999, where the EC granted the Institute of Professional Representatives (EPI), a European professional body grouping patent agents, a negative clearance under Art. 101-1 TFEU concerning most provisions of its Code of Conduct on the ground that these provisions aimed "to ensure impartiality, competence, integrity and responsibility on the part of representatives, to prevent conflicts of interest and misleading advertising, to protect professional secrecy or to guarantee the proper functioning of the European Patent Office" (point 38)."

3 Information exchange. Members must never, neither at formal gatherings nor at other informal meetings, exchange confidential or otherwise competitively sensitive business information. Eucomed cannot be used as a forum to discuss such topics either. Subjects which must never be discussed are:

- Prices, discounts, or price-related contractual terms. This includes planned or implemented price increases (whether or not a precise amount of the increase is included), the dates of planned price increases or announcements, mark-ups, rebates, allowances, credit terms, promotions, or any other data that would have a bearing on price (e.g. costs, production volumes, capacity, inventories, sales). Government-imposed prices and reimbursement policies are not included in the subjects to be excluded but, negotiation tactics vis-à-vis government agencies with respect to prices and reimbursement must not be discussed either;
- Client relations and customer credit risk, including among others the identities of individual customers or sales territories;
- Contract tenders, ongoing bids or plans to bid for business as well as the corporate procedures for responding to tenders;
- Business plans or commercial strategy and forecasts of market evolution;
- Competitive strengths/weaknesses in particular areas;
- Production planning or output levels, including inventory/order backlog;
- Individualised data about production volumes, sales or capacity. It is particularly important that such data is not exchanged in relation to specific competitors (e.g. the top three producers for a particular sales segment in the last quarter).
- Product development or investment in research programs which is not yet publicly known;
- Individualized market share data.

Benchmarking, i.e. compilation and circulation of statistical data and/or exchange of information is allowed, if and only if, the following conditions are respected and advice from outside legal counsel is sought:

- The entity collecting, aggregating and circulating the data is neutral and bound by confidentiality, and

- Only aggregated data is circulated to participants and competitively sensitive information such as market shares and export volumes remain anonymous. Individual company data must not be circulated and it must not be possible to derive individual company data from the aggregated data circulated (i.e. to disaggregate it).

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 without the presence of an appropriately trained Eucomed Secretariat member or legal counsel, and allow open and voluntary participation in the exchange. Exchanging certain types of sensitive information may be more anti-competitive than other forms of exchange of information².

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

A company may be in a dominant position if it can act to an appreciable extent independently of its customers and suppliers in a given market. A dominant position is not in itself anti-competitive, but if the company exploits this position to eliminate competition, it is considered to have abused it. 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 overprice, 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 five or fewer of them account for a large share of supply and if they have contacts with each other through the trade association. Dominant

² Eucomed has requested extensive and ongoing external legal counsel to provide competitive assessment under EU competition law of the information exchanged through the various Market Surveys undertaken and/or managed by Eucomed.

positions can be held by single firms and, in certain circumstances, held collectively. In other words, Article 102 TFEU can apply to oligopolies. 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 an anti-competitive object or effect, without objective justification, fines and civil liability may result. There is no need to demonstrate the existence of an agreement or collusion. Examples of possible abuse of dominance include:

- Charging unreasonably high prices;
- Imposing excessive or discriminatory terms on customers or suppliers;
- Depriving smaller competitors of customers by selling at artificially low prices they can't compete with;
- 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;
- Obstructing competitors in the market (or in another related market) by forcing consumers to buy a product which is artificially related to a more popular, in-demand product;
- Refusing to deal with certain customers;
- offering special discounts to customers who buy all or most of their supplies from the dominant company;
- Making the sale of one product conditional on the sale of another product.

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. In case the agenda contains inappropriate discussion items, express your concerns 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, ensure that a record is kept of your disagreement and leave the meeting. 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 legal counsel, who will take appropriate steps. Should you not have a legal counsel, immediately contact Eucomed's legal counsel.

E. Procedure for Eucomed meetings

Eucomed Secretariat shall take every reasonable precaution to ensure that meetings are managed in such a way as to ensure that the risks of inappropriate discussion taking place are minimised.

As a practical matter, therefore, Eucomed undertakes the following:

- Eucomed shall post these Guidelines on its website (www.eucomed.org) so that members and the public have access to it.
- Written agendas for each Eucomed meeting must be drafted and circulated prior to the meeting and every agenda will contain, as its first and standing item, a competition law reminder.
- Either the working group/taskforce chairman or the Secretariat representative will make sure that all participants are aware of EC competition law obligations and the fact that all Eucomed meetings will comply with it. This will be recorded in the minutes of the meeting.
- Comprehensive minutes of each meeting will be drafted and any comment or request for amendment will be notified to the meeting chairman and to Eucomed Secretariat person in charge as soon as possible following receipt of the minutes.
- In each meeting, a list of participants, including the competition law Dos & Don'ts, shall be circulated during the meeting and signed by all participants. The list shall be appropriately filed by the Secretariat. The list of participants shall be included in the meeting minutes.
- Eucomed shall keep agendas, minutes and attendance lists of every meeting chronologically.
- Eucomed shall give meeting participants access to agendas and minutes of the meetings they have attended upon request.

ANNEX I: Guidelines on participation in Eucomed meetings ("Dos and Don'ts")

■ 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 clear indication of the purpose and/or written agenda, circulated in advance.
3. **Don't** attend unscheduled gatherings unless you know that they are for a bona fide purpose or purely social gatherings.
4. **Don't** use Eucomed as a venue to engage in conduct that could be construed as intended to exclude competitors from the market or create a barrier to market entry.
5. **Don't** accept written non-public information or agree to the exchange of oral non-public information with members who market competing products.
6. **Don't** participate in information exchanges, market surveys, or benchmarking exercises without the advice of your and Eucomed's legal counsel.
7. **Don't** engage in negotiations, joint sales or joint buying without legal advice.
8. **Don't** exclude competitors or engage in collective boycotts.

■ DO's

1. **Do** identify clearly the specific legitimate purpose of each Eucomed project, meeting and conference call.
2. **Do** carefully read the Eucomed Compliance & Competition Law Guidelines that precede this Annex.
3. **Do** object to any discussion, activity or conduct that may infringe EC competition law rules and inform Eucomed if you disagree with any of its decisions and keep a copy for your files of any such correspondence.

4. **Do** stop any meeting when the participants insist on discussing matters that may lead to violations of EC competition law rules.
5. **Do** return commercially sensitive information you receive, without keeping copies, and explain in writing that you do not wish to obtain such information.
6. **Do** inform your company counsel and Eucomed of any approaches seeking to exchange non-public information or coordinate conduct on the market.
7. **Do** ask Eucomed to have counsel attend meetings if you or your company have any doubts.