MedTech Europe's Competition Law Guidelines

MedTech Europe Board approved on 29 April 2017

Introduction

Under Article 10 of the MedTech Europe Statutes, Members of MedTech Europe commit to act in compliance with the MedTech Europe Competition Law Guidelines ("Guidelines"). The Guidelines aim to give a thorough introduction to European Union ("EU") and national competition law and to identify the sensitive areas for cooperation between Members of MedTech Europe.

The Guidelines apply to MedTech Europe, including individual Members of MedTech Europe, and all committees, taskforces and ad-hoc groups ("the MedTech Europe groups") within MedTech Europe, irrespective of size and name.

All working groups, taskforces or any other member meetings labelled as "MedTech Europe meeting" whether inside or outside MedTech Europe premises, will be attended by a Secretariat Representative, appropriately trained in competition law. If no Representative of the Secretariat is available, external legal counsel will be appointed at the costs of the working group/taskforce members. Appointment of external legal counsel must be discussed with MedTech Europe's Legal Department prior to any commitment.

As a reminder, Dos & Don'ts (see Annex I) will be circulated and signed at each MedTech Europe meeting.

A. The prohibition of anti-competitive agreements

Horizontal agreements between actual or potential competitors which restrict competition between EU Member States are forbidden under Article 101 (1) TFEU whether formal or informal. Thus, no Member of MedTech Europe should ever discuss or be involved in any of the following activities:

- ***Price-fixing or any discussion on prices***, but also, and not limited to, the coordination of other pricing elements, including discounts, rebates, bonuses, surcharges, accounting procedures, terms of payment or profit margins;
- ***Market partitioning/sharing***, such as the allocation of customer groups or territories between competitors;
- ***Bid rigging agreements***, whereby competitors agree on terms and conditions to be submitted in response to a bid including pricing information, who should bid or win the bid;
- ***Output limitation***, 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;
- **Joint or collective boycott** whereby competitors agree not to deal with competitors, suppliers or customers.

Other agreements with competitors may raise competition law concerns and need to be reviewed by your legal department in advance. These include for example: joint negotiations, joint selling, joint purchasing, managed services.

Members of MedTech Europe should also refrain from exchanging competitively sensitive information, for example, any elements of pricing or costs, business plans, customer or supplier information or ongoing or planned bids (see section on Information Exchange for more detail).

An agreement or a decision of an association of undertakings does not need not to be written or binding to be prohibited by competition law. A verbal information exchange or an informal agreement can be an infringement even if it is merely a "gentleman's agreement". In addition, an agreement does not need to be implemented in order to be unlawful. A potential anti-competitive effect is sufficient.

B. Specific rules of conduct within a trade association

There are two specific areas that require particular attention when Members of MedTech Europe interact with each other in the framework of MedTech Europe:

1 - **Industry standards** - MedTech Europe or the MedTech Europe groups within MedTech Europe may develop and promote industry standards, codes of practice or standard terms and conditions for agreements. Standards are generally pro-competitive as they define ethical, technical or quality requirements with which current or future products or services may comply and improve the functioning of the market. However, neither MedTech Europe nor its Members should use standards as a cover to exchange commercially sensitive information or to restrict competition. External legal counsel should be sought if necessary when discussing development of standards. Accordingly:

- Standards must be related to specific legitimate objectives and should cover no more than what is necessary to achieve these objectives;
- As a general rule, standard-setting should not be used to:
  - Reduce or eliminate price competition;
  - Limit technical development or innovation;
  - Harm competitors by unfairly denying access to the standard.
- To that effect:
  - Standards should not be used to raise barriers to entry to the market or to exclude competitors from the market;
  - Participation into the standard-setting should be unrestricted and non-discriminatory;
  - Standard adoption procedures should be transparent;

2 - **Information exchange** - Members of MedTech Europe must never, either at formal meetings (within MedTech Europe or otherwise) or at other informal gatherings, exchange confidential or otherwise commercially sensitive information (non-exhaustively listed below) among each other or with other competitors. MedTech Europe cannot serve as a facilitator for such information exchange. Members of MedTech Europe should not discuss or exchange directly or indirectly:

- 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 can be discussed but, negotiation tactics vis-à-vis government agencies with respect to prices and reimbursement cannot be discussed;
- Individualised data about production volumes, sales or capacity;
- Customer or supplier relations and customer or supplier credit risk, including among others the identities of individual customers or suppliers or sales territories;
- Tenders, ongoing bids or plans to bid for business as well as procedures and terms (including prices) for responding to tenders;
- Confidential business plans or commercial strategy and individual forecasts of market evolution;
- Competitive strengths/weaknesses in particular areas;
- Production planning or output levels, including inventory/order backlog;
- Product development or investment in R&D programs which is not yet publicly known;
- Individualised market share data.

Benchmarking, i.e. compilation and circulation of statistical data, is generally allowed, if and only if, the following conditions are respected and advice from external legal counsel is sought:

- The entity collecting, aggregating and circulating the data is neutral and bound by confidentiality (e.g. trade association such as MedTech Europe or any other third party such as consultancy firms); and
- Only aggregated (at least including 3-4 participants depending on the number of companies on the market) and historic data (at least 1 year old depending on stability of the market) is circulated to participants and competitively sensitive information such as sales, or market shares remain sufficiently anonymous. Individual company data must not be accessible or otherwise circulated and it must not be possible to reverse-engineer the aggregated data into individual company data.

If a Member is part of a benchmarking exercise 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 MedTech Europe Secretariat Representative, a member of MedTech Europe's Legal Department or an external legal counsel. Participation in such benchmarking exercises should be open and voluntary.

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 hold a dominant position if it can act to an appreciable extent independently of its competitors, its customers and suppliers in a given market. A dominant position is not in itself anti-competitive. But abusing that dominant position to exploit customers or harm competitors is illegal.

Market shares on a relevant product and geographic market are used to assess dominance. A company is presumed dominant with over 50% market share (subject to showing rebutting evidence) and can be found dominant with market shares as low as 40% market share. Additional factors indicating dominance include: the fact that rivals are much smaller or that there are significant IP, reputational or financial barriers to competing in the segment. In the medical sector, companies have been found dominant in narrow markets and Members of MedTech Europe should therefore ensure they are aware of products or services for which they might be found dominant.

Examples of possible abuses of dominance include (there is no exhaustive list):

- Tying i.e. making the purchase of the product in respect of which the company is dominant (the tying product) conditional on the purchase of other products (tied products);
- Bundling i.e. offering discounts conditional on a customer purchasing two or more distinct products together;
- Exclusivity i.e. entering into agreements with customers or distributors which require them to buy only from the dominant company or a supplier nominated by it;
- Loyalty rebates i.e. offering rebates that have the effect of tying that customer to the dominant company;
- Predatory pricing i.e. offering below cost prices to eliminate a competitor from the market or make it difficult for a new competitor to enter the market;

- Discriminatory pricing i.e. differentiate in prices or terms and conditions of sale between customers unfairly in respect of the products with which the company is dominant;
- Excessive pricing i.e. charge excessively high prices to customers;
- Refusal to supply an indispensable input to a customer which would prevent it competing effectively and lead to consumer harm.

D. What to do if you suspect a breach of these Guidelines?

Mere presence at meetings where anticompetitive conduct is discussed can be enough to infringe competition law. To avoid a possible infringement, check the agenda (there must always be a written agenda) and object in advance to what appears non-compliant after consulting with your legal department. In case the agenda contains what appears as inappropriate, express your concerns and stay away if the agenda is not amended accordingly.

As soon as you become aware of improper discussions or a possible infringement, contact your legal department, express your disagreement, ensure that a record is kept of your disagreement by the MedTech Europe Secretariat Representative and if the discussions continue, leave the meeting and ensure that your departure is recorded in the minutes. If you miss a meeting, check the minutes upon receipt, and notify your legal department if the minutes suggest improper discussions or a possible infringement occurred. If there is a possibility that sensitive matters are discussed during meetings, consider asking in advance that an external legal counsel is present at meetings.

If you are uncertain whether a particular agreement, discussion or information exchange between competitors is allowed, immediately contact your legal department who will take appropriate steps. Should you not have a legal counsel, contact MedTech Europe's Legal Department.

Annex I: Guidelines on participation in MedTech Europe meetings ("Dos & Don'ts")

DON'Ts

1. **Don't** reach understandings, agreements, hold discussions or share directly or indirectly with a competitor commercially sensitive information such as prices, credit terms and billing methods, 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 involving competitors unless you know that they are for a *bona fide* purpose or purely social gatherings.

4. **Don't** exclude competitors from the market, jointly boycott or create a barrier to market entry or use MedTech Europe as a conduit for doing so.

5. **Don't** accept written non-public commercially sensitive information or agree to the exchange of oral non-public commercially sensitive information with competing MedTech Europe Members.

6. **Don't** participate in information exchange, market surveys, or benchmarking exercises without the advice of your legal department and MedTech Europe's Legal Department.

7. **Don't** engage in negotiations, joint sales or joint buying without consulting first your legal department.

DOs

1. **Do** carefully read and understand the MedTech Europe Competition Law Guidelines.

2. **Do** identify clearly the specific legitimate purpose of each project, meeting and conference call of MedTech Europe.

3. **Do** object to any discussion, activity or conduct that appears to infringe competition law and inform the Chief Executive Officer of MedTech Europe (and MedTech Europe's Legal Department) if you disagree with any of the decisions taken by MedTech Europe 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 infringe competition law.

5. **Do** return commercially sensitive information you receive and explain in writing that you do not wish to obtain such information after consulting your legal department and keep the correspondence and the source of the information.

6. **Do** inform your legal department and MedTech Europe's Legal Department of any contact from competitors outside or within MedTech Europe seeking to exchange non-public commercially sensitive information or coordinate conduct on the market.

7. **Do** ask MedTech Europe's Legal Department to attend any meetings if you or your company have any doubts.