



Technology: Medical device companies may see increased regulation

International trade association codes of conduct and their requirements

BY JESSE WITTEN

The two largest American medical device industry trade associations, the Advanced Medical Technology Association (AdvaMed) and the Medical Device Manufacturers Association (MDMA), have both adopted codes of ethics covering interactions with health care professionals (HCPs). For example, the AdvaMed code of ethics describes how companies can structure legitimate consulting agreements with HCPs, prohibits companies from providing entertainment and recreation, prohibits gifts to HCPs with a limited exception for educational items and allows for modest meals under certain circumstances. The AdvaMed Code also covers a number of additional topics, such as company support of third-party educational conferences, sales, promotional and other meetings with HCPs, research and educational grants, charitable donations and the provision of evaluation and demonstration products. The AdvaMed and MDMA codes have been widely adopted by their member companies and have been influential in establishing industry norms of behavior, but the codes are voluntary. Following the association's code is not a condition of membership in the association.

Foreign medical device trade associations have adopted similar codes. For instance, Eucomed, MEDEC and the Medical Technology Association of Australia (MTAA)—the leading associations in Europe, Canada and Australia—have all adopted codes of ethical business practices. The Eucomed and MTAA codes also cover antitrust and competition issues, as well as interactions with HCPs. Although the Eucomed, MEDEC and MTAA code provisions regarding interactions with HCPs are generally similar to the American codes, there are some differences.

One significant difference is that the Eucomed and MTAA codes are mandatory. Adherence to their codes of ethical business practices is a requirement for membership in those organizations. Eucomed's membership includes 25 European national device industry trade associations and thousands of companies. A Eucomed member company must comply with the code of the national association in which it is located and in which the promotion or interaction with an HCP occurred. If a member company is located in a territory that lacks a member national association, or if the national association lacks a code of ethics, then the company must follow the Eucomed Code of Business Practice as a default code.

In addition, both Eucomed and MTAA contain mechanisms to investigate complaints against member companies and to enforce code violations. In June, Eucomed revised its enforcement procedures, which are set out in a document titled "Eucomed Code of Ethical Business Practice: Procedural Framework." Eucomed's procedural framework requires that its national association members include within their national codes of conduct provisions for imposing sanctions for breaches of the national code.

The procedural framework requires that each of the 25-member national associations establish a compliance panel to handle complaints about member companies. Eucomed further "strongly recommends" that the compliance panels have non-industry chairpersons and not consist solely of industry members.

The Eucomed Code Committee reviews each national association's code to ensure that the national code and enforcement provisions "match substantially" the Eucomed Code of Business Practice. In countries where Eucomed does not find the national code to be adequate, or where there is no national association, the Eucomed Compliance Panel handles complaints and assesses sanctions in accordance with the Eucomed Code of Business Practice.

Complaints that a Eucomed member has violated the Eucomed Code of Business Practice or a national association's code could come from customers, consumers, competitors or any other source, and may be lodged either with Eucomed or with the national association. Eucomed refers complaints to the relevant national association, or to its own compliance panel for countries where Eucomed believes there is no adequate national association code. Eucomed's procedural framework states, however, that the dispute resolution procedures shall not preclude companies from seeking recourse in the courts.

The Eucomed procedural framework does not clearly spell out the procedures compliance panels must follow, but sets forth more general guidelines. It states that each member association shall "respect fair procedure rules allowing all parties to be heard fairly." The procedural framework also provides that, in the first instance, a complaint should be handled through mediation if an amicable resolution appears possible. When a complaint cannot be resolved through mediation, each member association's compliance panel renders its decisions and pronounces sanctions

on the basis of the national code of conduct, although a compliance panel should suspend activities in case of a formal investigation or enforcement by government authorities.

If a compliance panel concludes that sanctions against a member company are warranted, the procedural framework sets out a number of potential sanctions. These include:

- A written reprimand
- Requiring that the offender take steps to conform to the national code
- Requiring that the offender hire (at its own expense) a third party to inspect and audit the offender's compliance systems
- Requiring the offender to recover items given in connection with product promotion
- Requiring the offender to publish or otherwise disseminate corrective or clarifying statements either to the public or to particular customers
- Withdrawing permission of an offender to use a certification of compliance logo or a similar accreditation
- Publishing the decision or sanctions imposed
- Barring representatives of the offender from holding elected office within Eucomed or within the national member association
- Expelling the company from membership in Eucomed or in the national association.

The Eucomed procedural framework directs national associations to publish final decisions concerning complaints and to provide the company name and details of the case if there is a serious or a repeated breach of the code of conduct. In addition, Eucomed directs its member national associations to publish summaries of main facts and conclusions of decisions that have precedential or interpretive value and are of international interest.

Finally, each member national association must submit an annual report to Eucomed on the association's handling of complaints and sanctions imposed during the prior year.

How vigorously Eucomed and the European national trade associations enforce violations of their codes of business conduct and how frequently complaints will be lodged remain to be seen. Eucomed, however, has created a procedural framework to permit enforcement by European trade associations.