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How to implement effective healthcare code compliance processes and controls?

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Pharma or medical device companies are exposed to certain healthcare compliance risks. While they work with healthcare professionals (HCPs) to inform the latest clinical information to treat patients in the best possible way, supporting the continuous medical education of HCPs and getting feedback from HCPs in advisory boards or expert panels to improve products, the various forms of interactions between pharma companies and HCPs are susceptible to corruption, conflicts of interest, or are not always in the best interest of the patient.

Some of the compliance risks—not exhaustive list—are:

- Paying HCPs for no services rendered—in return HCPs prescribe the product(s) of the pharma company;
- Paying HCPs in excess of fair market value for the services rendered (e.g., speaker agreement, consulting agreement, advisory board participation, market research);
- Offering HCPs luxurious accommodation and lavish meals/dinners;
- Paying for HCPs' extra hotel nights during scientific conferences;
- Providing money to an event organizer to sponsor a scientific event not used entirely for scientific purposes;
- Giving HCPs gifts;
- Organizing scientific events in tourist locations; and
- Not keeping event agenda purely scientific, adding in leisure activities (e.g., sightseeing trips).

Due to such risks, various industry associations such as the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), European Federation of Pharmaceutical Industries and Associations (EFPIA), Pharmaceutical Research and Manufacturers of America (PhRMA), Advanced Medical Technology Association (AdvaMed), and MedTech Europe have each put together a code of ethics that defines the interactions between healthcare providers and pharma companies or medical device companies. Typically, such codes of ethics, or codes of practice, contain specific wording regarding:

- Continuous medical education of HCPs;
- Organization or sponsoring of events/congresses with HCPs;

- Speaker/consulting agreements with HCPs;
- Advisory boards;
- Educational grants to HCPs;
- Samples, gifts, promotional items to HCPs;
- Donations; and
- Working with patient organizations.

By becoming a member of IFPMA/EFPIA, PhRMA, and/or AdvaMed/MedTech, pharma or medical device companies voluntarily agree to abide by the principles laid down in the code of ethics. For example, any HCP, company, or member of the public may file a complaint reporting a breach of any provision of the IFPMA Code of Practice.[1] Then, IFPMA, or another respective industry association, will typically validate the complaint, investigate, and obtain feedback from the company involved. Where a breach occurred, it might (a) publish a summary of the case on its website or have an advertisement in the medical or pharmaceutical press, (b) publish a public reprimand, (c) request the company take corrective steps to avoid this happening again, (d) have an external company conduct an audit of the company's healthcare compliance processes, and/or (e) could even suspend or expulse companies from membership in the trade association.