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How to implement effective healthcare code compliance processes and controls?

By Patrick Wellens, CCEP-I, CIA, CFE, CRMA, MBA


Patrick Wellens

Patrick Wellens (patrickwellens@hotmail.com) is currently working as a Compliance Manager for a division of a multinational pharma company, based in Zurich, Switzerland. He is a Board Member of Ethics and Compliance Switzerland and co-chair of the working group "life sciences."

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.

In addition to the codes of ethics, the Physician Payments Sunshine Act, EFPIA Code of Practice, Loi Bertrand, and other regulations require pharma companies to disclose publicly any transfers of value that were made to HCPs or healthcare organizations (HCOs).

Pharmaceutical or medical companies with a global footprint operating in more than 100 countries can easily have tens of thousands of interactions with HCPs or HCOs. The information needed by compliance officers to approve a donation is not the same as approving an educational grant and/or approving the sponsoring of an event. Therefore, the question arises: What processes, resources, and controls do compliance departments of pharma companies have to establish to ensure compliance with healthcare code requirements?

What processes are needed?

Regardless of the organization of the compliance department (divisional, regional, central/decentral), it must at a minimum have the following information to evaluate code compliance requests by business functions.

- **Fair market value (FMV) table**, which describes country-by-country hourly rates that are considered FMV when services are provided by HCPs to pharma or medical device companies. Clearly the FMV tables need to consider different therapeutic areas (e.g., oncology, gynecology, dermatology) and different FMVs for local, regional, or international key opinion leaders.
- **Table with country-by-country details on maximum thresholds for meals (lunch/dinner) and drinks**. The aim here is to provide reasonable—not excessive—meals.
- **Country-by-country information about whether the approval of the HCPs' employer is needed** for engaging with an HCP.
- Prior to organizing or sponsoring an event with HCPs, in some countries an approval by the local ministry of health is needed, requiring **a table with country specifics**. The country specifics should include whether an approval by local ministry of health is needed, the notice period, and what type of information is to be provided.

- **Documentation repository** to upload relevant information (e.g., event agenda, written request for sponsoring by external party that wants to be sponsored, budget for sponsored event, document explaining the reasons for and use of educational grants).
- **Contract (management) depository.**

What controls are needed?

- For all interactions with HCPs, a written document/contract should exist. It should not be possible for business functions to engage HCPs and authorize payments without a written contract.
- In the case where the legal and (code) compliance department are different, the legal department should ensure that a code compliance approval is available prior to engaging in a contract with an HCP or an HCO.
- As code compliance rules apply to the country where the HCPs is practicing, for international congresses/events, satellite symposium, or advisory boards with HCPs from various countries, approval from code compliance officers in various countries is needed. The pharma company must have an approval workflow to document the various country code compliance approvals.
- The code compliance officer is responsible to ensure that FMV tables, maximum thresholds for meals, and reporting requirements to local authorities are kept up to date, and, prior to giving compliance approval on an interaction with an HCP/HCO, they must verify against the principles laid down in the code of ethics of the industry association the company is part of.

What resources are needed?

The type and number of resources needed depends on how standardized the IT system and workflow are and whether approval is done locally or centrally.

Option 1

The company does not have a global application/IT system, but rather each country has developed its own IT solutions (e.g., standardized Word or Excel templates) and workflows to document the code compliance approval for interactions with HCPs or HCOs. In each country, the pharma company has appointed a healthcare compliance officer who needs to approve all interactions with HCPs. For each of the interactions with HCPs, the business completes a form and sends it to local compliance officer for approval.

Advantage	Disadvantage
The business functions have a local central point of contact for all questions and approvals related to healthcare code compliance.	The local countries might have different processes and approval workflows for code compliance, so there is no global uniform standard.
	The global compliance department does not have visibility and insight into all transactions.

	Due to the lack of a centralized system/platform, no data analytics or other reporting can be applied to evaluate efficiency of operations.
	Auditing/monitoring of healthcare code compliance transactions in all countries by a central team is not possible due to the lack of a centralized IT system/platform.
	There are higher IT maintenance costs (servers, backups, etc.) than a global application.

Option 2

The company does not have a global application/IT system to document the code compliance approval for any interactions with HCPs or HCOs; each country has developed its own solution and workflow. The pharma or medical company does not have a compliance officer in each country but works with regional compliance officers. Regional compliance officers approve all interactions with HCPs.

Advantages	Disadvantages
A regional officer concept creates economies of scale and might be advantageous if the region consists of countries where there are limited interactions with HCPs.	The business functions in each country do not have a local (rather regional) central point of contact for all questions/approvals related to healthcare code compliance. The regional compliance officer might not be aware of all code requirements or code updates in each of the countries of the region.
	If there is no centralized uniform system implemented in all countries of the region for the code compliance approval transactions, data analytics and auditing/monitoring by a central team is not possible.
	There are lower maintenance costs than a fully decentral application but higher costs than a global application.

Option 3

The company has a global IT system/application for some interactions with HCPs/HCOs, with an integrated country-by-country compliance approval workflow. For other interactions with HCPs/HCOs, the company does not have a global IT system, and various templates and approval processes exist in each locality.

Advantages	Disadvantages
One central platform: IT maintenance costs are restricted to one application only.	To accommodate local legal or code requirements in a centralized platform, a substantial one-time effort is needed to customize the IT platform.
The workflow approval is integrated into the application.	
There is visibility on quantity and type of interactions with HCPs/HCOs.	
Centralized auditing/monitoring is possible.	

Option 4

The company has a global IT system/application for interactions with HCPs/HCOs with an integrated approval (by local compliance officer) workflow.

Option 5

The company has a global IT system/application for interactions with HCPs/HCOs with an integrated approval (by regional compliance officer) workflow.

Option 6

All interactions with HCPs/HCOs are uploaded into a central IT platform or application with an integrated approval (by global compliance team) workflow.

For options 4–6, the advantage of the centralized platform is that the global compliance function has visibility on quantity and type of interactions; can apply data analytics, centralized auditing, or monitoring; and can incur lower IT maintenance costs. When compliance approval is done globally or regionally rather than locally, the challenge for the global or regional teams is to understand the local code requirements.

Option 7

All interactions with HCPs/HCOs are uploaded into a central IT platform/application with an integrated code compliance workflow approved by a global or regional team. The compliance approval workflow is automated (i.e., a substantial number of transactions with HCPs are not reviewed manually anymore). Only those transactions that are high risk or where a mandatory document is missing are reviewed manually.

Conclusion

Global pharma or medical device companies could have tens of thousands of interactions with HCPs or HCOs. To maintain their reputation and avoid public reprimands or negative press, they must implement processes and controls to comply with the code of practice/code of ethics of industry associations they became a member of.

Rather than having each country affiliate develop its own software solution and code compliance approval workflow, pharma and/or medical device companies can increase the effectiveness of code compliance processes and controls and the efficiency of compliance resources by implementing a global IT system with integrated compliance approval that includes standardized processes for the approval of interactions with HCPs/HCOs.

By having a standardized process with minimum mandatory documents and information to be completed by business functions requesting code compliance approval, the global compliance function obtains full visibility of all transactions, can apply data analytics or reporting, and can apply economies of scale when conducting compliance monitoring or auditing. In an even more advanced stage, the manual approval by a code compliance officer can be replaced by an automatic system approval for a substantial number of low-risk transactions.

Takeaways

- Pharma and/or medical device companies need to abide by various industry codes of ethics or codes of practice standards for their interactions with health care professionals (HCP) or healthcare organizations (HCOs).
- To increase efficiency and internal controls, it is recommended that companies have global standardized processes and templates for healthcare code compliance transactions, including compliance approval workflows.
- A centralized IT platform gives the compliance department full visibility into the quantity and values of interactions with HCPs.
- Ideally the centralized IT platform is linked with the company's contract management system so that contracts with HCPs/HCOs are only created and signed after the compliance approval happened in the centralized application.
- Companies can further improve the use of compliance resources by reviewing only those interactions with HCPs/HCOs that are high risk. Low-risk transactions can be approved automatically following a decision tree logic.

1 "Ethics and Business Integrity: IFPMA Code of Practice (2019)," International Federation of Pharmaceutical Manufacturers & Associations, accessed March 11, 2022, https://www.ifpma.org/subtopics/new-ifpma-code-of-practice-2019/.