Guidehouse

Life Sciences

Key Takeaways From Pharmaceutical Compliance Forum's Covid-19 Pandemic Action Plan Webinar For Pharma And Medical Device Ethics And Compliance Teams

Compliance officers from the life sciences industry joined together recently to discuss how the COVID-19 pandemic has changed the ways we live and work, and how those changes have impacted the life sciences industry as a whole and will continue to do so in the future. From there, leaders discussed ways that life sciences companies can find a "new normal," moving forward in the various roles that Ethics and Compliance must take relative to three critical topics. Guidehouse has summarized these key considerations below:

Topic No. 1: Prioritizing Patients

A public health crisis can impact delivery of care to current and future patients. The pandemic also potentially makes each of us a COVID-19 patient. In this intersection, Ethics and Compliance officers must:

- **Plan for disruptions in the supply chain in order to reduce the impact.** Plan in advance for determining priorities when shortages occur; who and how will you communicate to the authorities; and plan for how to support compassionate use programs and clinical trials.

- **Reemphasize the importance of patient privacy.** Privacy laws remain in effect and could impact employees who do not regularly deal with privacy matters. How will your company handle actual and potential COVID-19 cases amongst your employees? Train the appropriate employees on communicating to state and local authorities, as well as the storage and communication of information.

- **Document the rationale and plan for price changes.** Price increases will be viewed skeptically. A top priority for companies should be to anticipate price changes so that business units and partners can evaluate price change impacts, document rationales for price changes, and plan associated mitigation actions. Be on the lookout for potential anti-kickback issues.

Topic No. 2: Supporting Physicians and Hospitals

Business as usual is not possible anymore. As the business adjusts in order to continue to meet the needs of its customers, Ethics and Compliance officers must:

- **Ensure safe access for your employees by communicating the risks in the new ways of doing business.** Should the business stop customer visits in highly affected areas? If not, is sufficient personal protective equipment and other necessary equipment available? Live monitoring may need to be shifted as well to account for any business operations that have moved to a virtual-delivery model.

- **Review the promotional activity of sales teams and evaluate incentives.** Changes likely will require a prolonged shift to e-detailing. Monitor physician responsiveness to this new virtual activity and adjust compensation plans accordingly.

- **Work closely with medical information departments to establish a cohesive crisis management plan.** As new safety information comes to light in this crisis, ensure that medical information employees are well-trained and continually informed on proper messages and responses for field inquiries.

- **Plan for the underreporting of adverse events.** Verify that adverse event reporting mechanisms are secure and communicate a top-down "better safe than sorry" message in terms of reporting.

Topic No. 3: Evaluating Existing Controls and Adjusting Risk Appetite

- **Perform a risk assessment to determine a company's adjusted risk appetite.** The use of virtual business models and e-detailing mechanisms can cause normal business processes to move more quickly. The nature of a public health crisis also requires that life science business operations move as quickly as possible, while still maintaining an appropriate level of control to manage risk. Evaluate all controls in place and determine which controls are absolutes based on your company's risk tolerance. Which controls can be adjusted or temporarily removed to accommodate a revised business process?

- **Communicate clearly and consistently.** Though work may be virtual, ensure cross-collaboration with other functions remains consistent. Report any areas of compliance concern through the appropriate channels.

- **Plan for the transition to the new normal.** When communicating revised business processes, be sure to communicate estimated implementation schedules and plans to return to normal business operations, when appropriate. Routinely conduct risk assessments when making any significant transition to review the current control environment.

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