Credible Compliance

Linda Horton takes a global look at some of the issues that are set to affect compliance in the coming year.

Compliance problems, as we all know, can tarnish the reputation of companies and the value of their brands. Restoring both a good name, and the customer's trust, can take years.

Executives have to pay attention to compliance and they know that, even for foreign operations, out of sight is not out of mind. In many companies, country managers once operated mini-fiefdoms. Today, however, many companies have decided that there is a need for certain top-down controls in the compliance arena. Otherwise, the legal, publicity and damage-to-brand risks presented by compliance failures are simply too great.

2008 and beyond

One of the pharma trends in the coming year and beyond is more attention to clinical trial compliance issues. At present, most companies have compliance plans and standard operating procedures (SOPs) governing both marketing practice compliance and relationships with healthcare professionals (HCPs). Clinical trials do not have as many clear guideposts, and certainly not the array of codes of practice seen at the post-market stage. Outside the US, there is little guidance for drug companies on relationships with clinical investigators and hospitals in a trial context. Sometimes, contract research organisations (CROs) will suggest a range of 'incentives' to motivate investigators to speed up enrolment of human subjects. Or they might ask for certain benefits, such as sponsorship to a medical conference. There is a general rule in the International Conference on Harmonisation (ICH) guidance on Good Clinical Practices that all financial arrangements in a trial must be disclosed to the Ethics Committee (Institutional Review Board). However, for trial sites outside the US, there is generally little other guidance on what assistance to a clinical investigator (equipment, training, reimbursement for travel to conferences and so on) is permissible.

Bribery. Another trend to watch is increased attention to healthcare 'bribery.' There has recently been an explosion of interest in the relevance of the US Foreign Corrupt Practices Act (FCPA) and other countries' anti-bribery laws to drug companies' relationships with HCPs who are either employed by foreign governments or who practice medicine in public hospitals. Whether it is a clinical trial agreement, a consulting arrangement, a market research study or speaker training, the stakes are higher when dealing with a government doctor. Certainly the entire area of bribery in the healthcare sector will continue to receive a great deal of attention.

Code revision. Pharmaceutical companies' operations are still implementing the 2006 revision of the marketing practices code of the International Federation of Pharmaceutical Manufacturers Associations (IFPMA). But now all European operations must once again adapt their practices, this time to match the 2007 version of the code of the European Federation of Pharmaceutical Industry and Associations (EFPIA).

Notably, the EFPIA revised code expanded its coverage of scientific and educational activities — the last version had focused on promotional activities as well as rules for hospitality at both promotional and educational meetings. One change that may make life simpler for companies is the provision stating that any funding to sponsor an HCP's attendance at an international congress is subject to the rules of the jurisdiction where the HCP carries out his/her profession, rather than the rules of the jurisdiction where the event takes place. Before, the disparities between the PhRMA code's limits on sponsorships for mere attendance at meetings — and the European code's permitting such sponsorships — had created confusion in the frequently occuring situation in which a multi-national drug company is sponsoring a European doctor to attend a medical congress in the US. Under the revised code, sponsorship to attend a medical congress must be in compliance with the laws and relevant codes of the country where a doctor practices.

Compliance plans and procedures

Without a doubt, the foundation for any compliance plan is the issuance of standards and policies to guide business conduct. Company policies need to use language and examples that can be readily understood by the business people who have to follow them.

Creation of a compliance plan is not primarily a drafting exercise to write down some ideal policies and then publish them. This seemingly common-sense and straightforward approach is, in fact, academic and idealistic. It can create organisational standards, without taking steps at the same time to change behaviour and internal norms. In the event of a problem, the gap between what the company says it does, and what its employees in fact do, can result in an enforcement nightmare — bad conduct as well as bad documents.

So you, as an executive, can set the tone by showing those who work for you that compliance is a non-negotiable priority. At the same time, avoid compliance plans that are unrealistic and unachievable. A better and more pragmatic approach begins with an assessment of the organisation's current understanding and approach to regulatory compliance, and building on that.

Many company compliance programmes establish risk-based priorities. A company code needs to be strictest on bribery issues, kickbacks, waste of public healthcare funds and tax evasion, as well as classic regulatory concerns including off-label claims, hospitality, congresses and payments to doctors. Executives and compliance professionals need to particularly watch out for situations where there could be accusations that a company's payments (or other benefits it provided) might have influenced the choice of products by public healthcare systems.

It is not simply enough, however, to issue policies and to train people. Companies also must take steps to assess the extent to which business conduct conforms to compliance standards. This is best accomplished through a system of monitoring and auditing. Monitoring and auditing serve to assure there is no gap between the plan and the reality. And there is need for consequences: an effective plan can help ensure that any improper conduct contrary to established written policy is isolated.

The better the procedures to implement the policies, the more likely that violations will involve instances of falsification or other forms of deceit by employees seeking to circumvent the policy. Typically, such a fact pattern puts an organisation in a much stronger position to address any questions from outside parties such as government bodies or trade code groups. The critical consideration is whether the organisation responds to violations in a way that is consistent with its overall compliance objectives. One aspect of a response is the application of appropriate discipline commensurate with the violation.

Credible compliance

To have credibility, disciplinary procedures must include everyone who participated in the violation in a material way, not just lower level employees. Also, the organisation needs to learn from its problems by taking steps to understand why and how the violation occured and identify changes in the procedures to avoid recurrences.

Finally, the organisation must determine whether the violation is of a type and scope to warrant some form of disclosure to regulators.

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