

Compliance in Pharma

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Let's face it, "compliance" is one of those catch-all terms that industry professionals use at will but whose meaning or the significance it carries is never fully explained. As a result, the term has attained an aura of mystery, although there really is nothing arcane about it. With the help of a few examples, this article will lay out the foundation for a better understanding of the term in the context of the pharmaceutical market in Russia.

The important message to take away is that compliance is not simply about making sure that your company is meticulous in following the array of laws and regulations that govern its day-to-day operations. Adequate and successful compliance is primarily about information flow. It is about how you build the information exchange system within your company — the system that helps follow the applicable laws, set internal rules, convey the necessary information "downstream," where compliance risks abound, and set up "upstream" response mechanisms to help gauge effectiveness and, essentially, stay on top of things.

Information flow is key to compliance. Yet, it is important to remember that compliance building and maintenance is not a one-off effort where information exchange, once set in motion, goes on in perpetuity. Effective compliance is high-maintenance and requires constant revision, update and monitoring to reflect both the company's internal dynamics and its position in a given market. And that is what makes compliance building so arduous and time consuming.

There is definitely a correlation between the complexity of pharmaceutical market regulation and what level of compliance is required. Pharmaceutical compliance plays a tremendous role in helping companies find the right balance between operating profitably and demonstrating a high level of responsibility in following pharma-related laws and regulations that are introduced, revised, or amended with a frequency that makes the heads of even the most seasoned industry specialists spin.

There are elements of pharmacy compliance that are essentially inward-looking. Take "access-to-doctors" rules, for example. In 2011, Federal Law #323 "On the Foundations of Health Care for Russian Citizens" set out new restrictions concerning how doctors and pharmacy professionals may interact with pharmaceutical companies and their representatives. While not sending shockwaves through the industry, the new rules made many a company revisit their marketing and sales practices and communicate the new rules to staff members and sales representatives. However, "downstream" communication is never enough compliance-wise, and companies now need to gather information "upstream" to find out whether the rules are followed despite peer pressure from competitors that may very well continue carrying out business the old way. Keeping an eye on legislative change is also a must. New amendments to Federal Law #61 "On the Circulation of Medicines" may introduce separate prohibitions against pharmaceutical manufacturers. Forthcoming revisions to the RF Administrative Code contain fines that will add punch to prohibitions and urgency to compliance initiatives.

Compliance can also be outward-looking. A key example of this is compliance with Federal

Law #135 "On Protection of Competition" and recommendations by the Federal Anti-Monopoly Service (FAS) that ask pharmaceutical companies — a priori dominant on their respective product markets, according to the FAS — to implement commercial policies for dealing with distributors and re-sellers. In other words, for pharmaceutical companies, the process of selecting a potential business partner is now a compliance-related task, with information exchange occurring not only inside a company but also between unaffiliated businesses.

Internal controls in the financial sector aside, the word "compliance" is not a common term in Russian law or enforcement practice, at least not yet. There is a new trend developing, however. More and more companies are shifting from being compliance-curious to compliance-focused. This is the way business operates globally to stave off liabilities and risks and to increase profitability. And as Russian companies continue to grow and look for partnership opportunities abroad, they find that compliance is instrumental to advancing their business interests further.

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