

## **Global Business Trend: The 5 Cs of Risk Management Communication**

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In the last 12 months, risk management communication has taken center stage as the FDA continues to enforce the need for Risk Evaluation and Mitigation Strategies (REMS). Products deemed to have serious risks can experience approval delays or even be removed from the market altogether, if the REMS is considered inadequate.

While the mechanics of REMS are now better understood, companies are just now identifying best practices for their development and execution. Below are five examples of where effective communication must factor into the entire process – from pre-approval to post-marketing.

### **Cross-functional Communication**

Global executives must actively communicate across cross-functional teams to manage risk throughout all drug development phases. Fully-informed drug development cannot tolerate silos, which inhibit the ability of internal stakeholders to effectively define and act on critical points for risk management. Working hand in hand, companies will become more sensitive to the implications of early planning on drug approval/marketing (cause and effect), engage in more effective long-term planning for product development and approvals, and be able to agree on sustainable process improvement.

### **Cross-Cultural Communication**

Communicating risk information and implementing risk management programs across diverse cultures is a daunting challenge for global corporations, wherever their home base may be. Cross-cultural awareness and planning are required to ensure consistent understanding of and response to risk information. This will occur only if communication professionals develop cultural competency so they can anticipate how risk messages might be filtered through diverse cultural perceptions and divergent criteria for evidence. The potential for misunderstanding and inappropriate response must be acknowledged, then proactively anticipated and prevented to the greatest degree possible.

### **Corporate Communication**

Corporations must effectively and proactively communicate risk information for any globally marketed product. Internal education on the details and the value of risk management programs helps ensure seamless implementation and execution. To anticipate and mitigate crisis situations resulting from announcements of adverse drug effects, internal preparedness planning must intensify.

Externally, healthcare professionals, media, patients, and the public must understand the purpose and the need for risk communications to protect the reputation of global brands. An essential component of the post-approval communication plan is

development and implementation of a strategy to frame a product's risk/benefit ratio before launch – and ongoing.

### **Creative Communication**

Experts in the field have made it clear: REMS is not just about getting the FDA to approve a product. Companies must recognize its pivotal role in keeping their brand from being taken off the market. With the proliferation of new media channels, marketers will need to disseminate risk management messages far beyond just a Medication Guide, Patient Package Insert or hospital and patient registries. This fundamental shift in perspective necessitates more creative execution of educational materials and programs to physicians, hospitals, and patients.

### **Compliant Communication**

While promotional regulations differ by country, the implications of noncompliance are far-reaching, including billions in fines, personal indictments, and a spiraling distrust of the industry. Everyone needs to be accountable for regulatory compliance, including communication agencies, who can no longer abdicate responsibility to clients. Clients must require agencies to invest in independent training and certification apart from company-provided information. Tightened budget belts are no excuse for putting this off – the stakes are too high. Sales reps are trained and tested periodically to ensure their knowledge of government requirements and voluntary codes. Training and testing for communication professionals must follow suit.