Life & Health

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CHINA'S WAKE-UP CALL FOR GLOBAL BUSINESS

The barrage of disclosures about GlaxoSmithKline's (GSK) China operations and other multinational companies has stretched across the summer. And while the story isn't finished, the disclosures carry many lessons for Life Science companies around the world.

1. The US' Foreign Corrupt Practices Act and the UK's Bribery Act remain two of the most powerful anti-corruption laws in the world but other countries are rapidly signaling their intention of taking bribery of government officials into their own hands, either by enacting new laws or boosting enforcement of existing laws. In August 2013, Brazil adopted the Clean Companies Act, the country's first anti-corruption law to allow enforcement against companies as well as individuals. Set to take effect in January 2014, the law is expected to apply to any company that does business in Brazil. Canada has also changed the playing field by revising its Corruption of Foreign Public Officials Act, expanding grounds for criminal liability, adding a "books and records" provision and prohibiting facilitation payments. Even without the emergence of new and tightened national laws, questions are already being asked about GSK's liability under the US' FCPA and the UK's Bribery Act.

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CHINA'S WAKE-UP CALL FOR GLOBAL BUSINESS *(Continued)*

2. According to a July 27th report in the UK's Sunday Telegraph, GSK had been informed in January about some of the same problems at the heart of China's investigation. The company quickly launched a four-month investigation into the allegations but found no evidence of corruption or bribery in its China business. The disconnect between the internal investigation and subsequent findings highlights the importance of thorough internal audits by all companies to identify possible cases of misconduct before they become serious problems.

   Since new and often locally specific compliance risks can emerge outside the watchful corporate compliance eye, companies are best served by developing and leveraging local compliance emissaries, training mid-management "eyes" to identify new potential issues.

3. Many observers suggest that the problems faced by many firms in China, including global companies with Chinese operations or subsidiaries, can be traced to compensation practices for sales reps. Tying sales to compensation has been common in countries including the US and EU member states. Recent CIAs between pharmaceutical companies and the US government have specifically included requirements to change to a non-volume compensation model, thereby reducing the use of financial incentives for achieving high sales numbers "by any means possible."

4. The risk for corruption and bribery has been well-known to all global Life Science companies that consider establishing a China operation. Poorly paid physicians, government-owned hospitals and one of the world's fastest growing markets for medical products appear to create an extreme risk for noncompliance with Chinese, US or UK laws. Any company that considers operations in China or similar economies should recognize the risk of corruption and develop compliance and ethics systems that specifically address the higher risk.

The fallout from this investigation has already been felt. More than six multinational pharmaceutical companies with operations in China are being investigated for violation of China's laws. The US and UK governments are being questioned about their intention to investigate GSK for violation of the FCPA and Bribery Act. Foreign companies in China, both inside and outside the medical products industry, have been put on notice for China's appetite for pursuing large, global companies for possible bribery. Risks from third parties in China, such as travel agencies, create extreme vulnerability for companies beyond the one originally investigated. While investigating GSK, Chinese police noted that a number of additional global companies had used the same travel agency, possibly to funnel bribes to government officials.

Sales have already been hurt for international and local firms, according to a September 18th report by Reuters, with "... many doctors at Chinese hospitals refusing to see drug representatives for fear of being caught up in the widening scandal." Reuters also reported that drug sales by international companies had slowed down, noting that, "The cutback in promotional activities has forced a number of drug companies to scrap monthly or quarterly sales quotas."

Notwithstanding the risks in China, the market is simply too big for global drug companies to ignore or abandon. What this case demonstrates, however, is that companies will have to change the way they do business in China, and many other countries are showing new dedication to anti-corruption initiatives. Perhaps most important, global companies will have to scrutinize their sales practices, procedures for internal audits and monitoring of foreign operations.

UL JOINS APEC MEMBERS IN GROUNDBREAKING BUSINESS ETHICS TRAINING INITIATIVE

Last month, more than 150 ethics trainers from the 24 Asia-Pacific Economic Cooperation (APEC) and the Association of Southeast Asian Nations (ASEAN) countries met in Kuala Lumpur for a program on the Business Ethics for APEC Small and Medium Enterprises (SMEs) Initiative. UL participated in the medical device and biopharmaceutical tracks of the far-ranging Initiative, both as a trainer and as a provider of content.

The Workshop is a crucial element of a long-term commitment by APEC and ASEAN nations and industry partners to establish open, ethical business environments throughout all member nations. SMEs form an essential engine for economic growth but only if they are able to operate and innovate in an ethical business arena. To promote a positive, ethical business environment, APEC SME Ministers issued a joint statement in September 2010 calling for APEC Codes of Ethics in key business sectors including medical devices and biopharmaceuticals. With the support of the US Department of Commerce, representatives of the medical device and pharmaceutical industries formed expert working groups to develop and publish APEC Principles for Business Ethics for each sector. All APEC ministers endorsed these principles and significantly approved funding in 2012 to support a multi-year program to build awareness among key stakeholders and implement the Principles for Business Ethics.

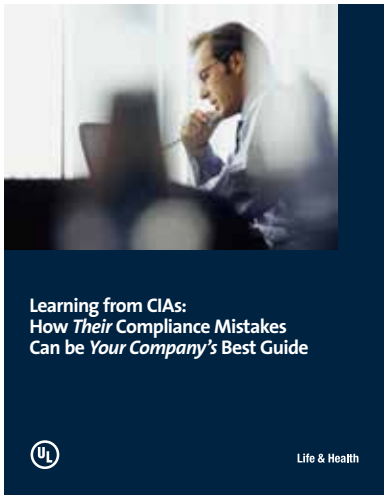
Following opening comments from the Malaysian Prime Minister, the program covered topics ranging from global trends in anti-corruption to transparency, cultural influences, the risks associated with healthcare professionals as government officials and the use of distributors. Proven strategies and tools to successfully implement compliance programs were shared. Among those tools: the use of ethics circles, branding the compliance program, and encouraging each business to "own" compliance. An AdvaMed EVP summed up the ambitious goals of the training program, saying, "We have assembled the largest network of compliance leaders in an area. These leaders are now expected to train their own industry member companies and HCPs within the next year."

UL was invited to participate as a trainer in the medical device program and develop online courses for the medical device and biopharmaceutical sectors to support the rollout of the new Business Ethics programs for APEC. We believe that Voluntary Codes of Ethics, along with the practical tools to assist companies to implement them, will provide a platform for effective industry self-regulation while supporting government anti-corruption efforts. As part of APEC's commitment to ethical business environments, UL will play a vital role through development of online content that will assist companies and governmental agencies to adopt a harmonized Code of Ethics and enable them to compete successfully across the APEC region and beyond.

LEARNING FROM NONCOMPLIANCE

Compliance is a challenge, no matter how long you've been in the field and how committed you are to continually improving your program and knowledge. One of the best sources of knowledge is your colleagues – and the mistakes they make.

In a new article, UL's SVP Ellen Leinfuss drills into some of the lessons we have learned through our experience with Life Science clients and our ongoing review of resources such as Corporate Integrity Agreements by Pharmaceutical and Medical Device companies. These reviews and analyses are designed to identify risks and effective responses for our clients. Included in the article is an analysis of the experiences of companies inside and outside the Life Science industry and a comparison of how their actions contributed to – or avoided – serious compliance problems.



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About UL EduNeering

UL EduNeering is a business line within UL Life & Health's Business Unit. UL is a global independent safety science company offering expertise across five key strategic businesses: Life & Health, Product Safety, Environment, Verification Services and Enterprise Services.

UL EduNeering develops technology-driven solutions to help organizations mitigate risks, improve business performance and establish qualification and training programs through a proprietary, cloud-based platform, ComplianceWire®.

For more than 30 years, UL has served corporate and government customers in the Life Science, Health Care, Energy and Industrial sectors. Our global quality and compliance management approach integrates ComplianceWire, training content and advisory services, enabling clients to align learning strategies with their quality and compliance objectives.

Since 1999, under a unique partnership with the FDA's Office of Regulatory Affairs (ORA), UL has provided the online training, documentation tracking and 21 CFR Part 11-validated platform for ORA-U, the FDA's virtual university. Additionally, UL maintains exclusive partnerships with leading regulatory and industry trade organizations, including AdvaMed, the Drug Information Association, the Personal Care Products Council, and the Duke Clinical Research Institute.