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Welcome to the third issue of Life Science Compliance. As a brief reminder, the aim of the Journal is to provide factual information and case studies regarding all aspects of Compliance for Life Science companies.

From this issue onwards, we welcome both Yuet Ming Tham and Kathleen Boozang as new members of our Editorial Board to help broaden our perspectives.

For issue 3, we have an eclectic mix of articles covering a wide range of topics from management of third party relationships to quality management systems.

Our first article in this issue is a paper from Eucomed and AdvaMed giving their joint guidance on ethical relationships with third party sales and marketing intermediaries. This article has been written by Aline Lautenberg of Eucomed and Christopher White of AdvaMed.

We then move into manufacturing compliance to look at the evolution of Quality Management Systems, with particular emphasis on the FDA’s requirements within the USA, written by Anita Fauchier of REDI Consulting.

Next, we travel to Asia for an article that looks at recent regional changes written by Lisa Thompson and Yuet Ming Tham of Sidley Austin.

The third in our series of Compliance Basics tutorials by Sue Egan discusses the role of the compliance officer and compliance committee, including potential backgrounds for compliance officers and the key skills they need to perform well in this vital role.

Our final article for this issue describes the first independent conference vetting system via EthicalMedTech, written by their compliance officer, Christine Sainvil. EthicalMedTech is a platform dedicated to ethics and compliance projects in the European medical technology industry and is supported by Eucomed.

We complete this issue with reviews of two recent conferences: the International Pharmaceutical Compliance Congress held in Budapest from 14th to
16th May 2012, and the Compliance Hub Conference held in London on 17th May 2012.

I would like to thank the members of the Editorial Board and all those who submitted articles for their assistance with this third issue of the journal.

I hope that you find this issue useful and informative. If you would like to contribute to future issues, or you have ideas for articles that would be of interest to our readers, please do get in touch with me.

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The World Health Organisation (WHO) believes that good health is essential to human welfare and sustained economic and social development. WHO’s Member States are committed to developing health financing systems to ensure that all people can use health services. For medical device, medical supply and other medical technology companies, this commitment requires the presence of life-saving medical technology around the world.

Medical technology companies embraced this need and most companies believe that a global presence is a strategic imperative. However, a global presence is a challenge for two reasons: (1) companies must build an international market and the medical technology industry is composed primarily of Small and Medium Sized enterprises (SMEs), and (2) companies pursuing global relationships are subject to considerable risk through the Foreign Corrupt Practices Act (“FCPA”) and other national and international anti-bribery rules. The FCPA is a U.S. law that prohibits companies from directly or indirectly (including through distributors) providing anything of value to “foreign officials” for purpose of obtaining or retaining business.

Summarized during the International Medical Devices Compliance Conference 2010, Kate Hamann, Trial Attorney, Fraud Section – Criminal Division, United States Department of Justice (DOJ), explained the compliance expectations of the U.S. Securities & Exchange Commission (SEC) and DOJ of the medical technology industry. In

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1 Only in Europe, there are 22,500 medical technology companies of these some 80% are SMEs employing less than 250 people. In fact, there are around 18,000 of these companies in Europe, more than half of which employ ten people or less.
particular, she highlighted industry risk with regards to business relationships with third parties. Companies will be held liable under the FCPA for the activities of their distributors.

**Global anti-bribery laws and FCPA**

FCPA was enacted to prohibit certain persons and entities to make payments to foreign government officials to assist in obtaining or retaining business. The Act has a broad reach and is also applicable to non-US entities and their agents engaged in transnational business that touches the USA, or whose shares are listed in the US. Moreover, the United Kingdom and many other countries have adopted similarly broad prohibitions on foreign bribery, including the 39 state parties to the Organisation for Economic Co-operation and Development (OECD) anti-bribery convention. Multinational entities based in highly developed countries must comply with anti-bribery laws broadly similar to the FCPA.

Under such anti-bribery rules, payments made to, or benefits provided to, physicians, nurses, technicians, or hospital administrators (referred to in the Eucomed and AdvaMed Codes as “Healthcare Professionals (HCPs)”) as part of a device company’s normal device development, education, marketing and promotional efforts may create criminal liability if structured improperly.

Important under global anti-bribery laws, entities and companies owned by foreign governments are *themselves* government bodies, meaning that improper payments made to an individual involved in the purchase, lease, use or prescription of medical devices could be considered bribery of a foreign official, even if the individual appeared to be a private citizen.

Under FCPA, companies may also be indirectly liable to criminal activity through the misconduct of foreign third parties, such as a company’s agents, intermediaries, consultants, joint venture partners, suppliers, distributors, local counsel, private equity portfolio companies and franchisees.

**Third Party Sales and Marketing Intermediary**

Medical devices are highly interactive
and differentiated products often requiring sophisticated users and unique service and distributor arrangements. Many medical devices are distributed through multiple smaller specialty distributors with technology-specific expertise. Many SME device companies depend on multiple overseas distributors to manage international sales. Given the realities of international business, many medical device and diagnostic companies do not inevitably work through their own direct sales force, but instead work with third parties to assist with marketing, sales and distribution.

Relationships with “Third Party Sales and Marketing Intermediaries” vary from company to company and may even vary within the same country and company, depending on different divisions and/or products sold. However, all companies experience inherent difficulty in managing these foreign third parties given cultural, language and local law differences. However, as mentioned above, companies are liable for these third parties, whatever form these relationships with sales and marketing intermediaries take, all may raise FCPA risk for companies unable to demonstrate compliance with anti-bribery rules.

To support its member companies and help them with compliance issues, last year the Advanced Medical Technology Association (AdvaMed) and the European Medical Technology Industry Association (Eucomed) approved guidance titled “Joint Guidance for Medical Device and Diagnostics Companies on Ethical Third Party Sales and Marketing Intermediary Relationships.” This guidance is intended to help all medical technology suppliers clarify responsible and ethical behaviour in high-risk areas and to provide best practices necessary to mitigate the significant legal exposure and reputational risk associated with international business.

**New Eucomed/AdvaMed Guidance**

The new guidance encourages companies to adopt a compliance program that integrates individual risk analyses and local laws to ensure ethical interactions between medical device companies and third party entities in marketing,
Joint Guidance on Ethical Third Party Sales and Marketing Intermediary Relationships

sales and/or distribution of products or services. Third party sales and marketing intermediary arrangements can be complex and implicate a variety of US, overseas and local laws. The guidance provides elements of a successful third party sales and marketing intermediary compliance program and serves as an important resource for any medical technology company engaging in third party sales and marketing intermediary interactions overseas.

The guidance identifies the following elements of an effective third party sales and marketing intermediary compliance program:

- Comprehensive anti-bribery policy;
- Established process for evaluating risk profiles of third party sales and marketing intermediaries;
- Risk-based pre-engagement and renewal due diligence program;
- Contract terms providing adequate controls and implementation of the policy;
- Training and education for third party sales and marketing intermediaries and the company employees that manage these relationships;
- Routine, risk-based assessment of third party sales and marketing intermediaries relationships; and
- Appropriate corrective measures when needed.

This guidance is the latest development in industry’s international and ongoing commitment to ethical business practices. In addition, the guidance complements AdvaMed’s as well as Eucomed’s Code of Ethics.

Eucomed and AdvaMed continue to assist industry in managing risk in this area. Next, the Associations plan joint implementation tools such as a third party sales and marketing intermediary due diligence list and common training materials. Successfully implemented guidance and tools will ensure ethical business relationships internationally, and will facilitate patient access to advanced medical technologies.
**Conclusion**

The guidance is intended to be read in addition to Eucomed’s and AdvaMed’s Codes of Ethical Business Practice. These codes provide broader recommendations on measures that companies undertake to make sure that their internal organisation and culture ensure ethical collaboration with Healthcare Professionals (“HCPs”) and prevent corruption.

For medical technology companies, interacting with HCPs is a key component of their day to day activities. HCPs are an integral part of the Research & Development process and a source of innovation and creativity during medical device development. HCPs are also the primary users of technologies and play an instrumental role in the successful adoption of innovative medical devices around the world. Companies are also required to provide HCPs with appropriate instruction, education, training, service and technical support to ensure delivery of modern, safe and effective medical technology and care to patients.

Together, the Codes and new third party sales and marketing intermediary guidance provide meaningful guidance to a dynamic, innovative industry to encourage ethical business practices and patient access to advanced technologies around the world. Minimizing FCPA and global anti-corruption risk begins with a commitment to the Codes and guidance and requires sustained commitment and effective implementation. From the platform provided by the guidance, companies are better positioned to meet the call of the WHO in meeting global patient needs.

*Aline Lautenberg, Eucomed Legal Counsel. Christopher White, AdvaMed Sr. EVP, General Counsel.*