Review of 7th International Pharmaceutical Compliance Congress and Best Practices Forum

Madrid, Spain, 21st – 23rd May 2013

Introduction

This article provides a review of the seventh International Pharmaceutical Compliance Congress and Best Practices Forum conference[1] held in Madrid in May 2013. It also looks at the wider context of other conferences, including the arguments for and against attending such conferences.

Conference Review

The previous six conferences have all been sponsored by the Pharmaceutical Compliance Forum (PCF)[2], a group of compliance professionals working in the pharmaceutical industry (see later for more information). This year, the conference was co-sponsored by PCF and a new organisation called ETHICS, the International Society of Healthcare Ethics and Compliance Professionals. ETHICS was launched in 2012 and has already attracted around 60 members from companies within the life science industry. It is a professional society run by compliance and ethics professionals for compliance and ethics professionals. You can get more information, including details of how to join, from their website www.ethicspros.com.

At the previous two annual events, held in Budapest in 2012 and Istanbul in 2011, the local industry bodies chose to launch new versions of their country codes. Whilst the Spanish industry body, FARMAINDUSTRIA, did not launch a new code, they did hold a full morning of free pre-conference training in Spanish with simultaneous English translation. This part of the conference was specific to Spain and included discussions on patient support programmes, fee for service arrangements with healthcare professionals (HCPs), and promotion of medicines through digital channels. Although the discussions related specifically to the Spanish industry Code of Practice, the topics discussed are current hot topics globally.

The main conference was opened with a panel of the conference co-chairs (Ann Beasley Bacon of Biogen Idec, Dominique Laymand of Bristol-Myers Squibb, and Roeland van Aelst of Johnson & Johnson) setting their vision for the conference and beyond. This included discussions around looking at culture as values based, rules shaped, and perception optimised to give the best possible outcomes for patients, HCPs, and life science companies alike.

Elvira Sanz, President of Pfizer Spain, gave the Gabor Danielfy Memorial Keynote Address[3], in which she highlighted the great advances in medicine that have dramatically reduced mortality rates. In particular, she highlighted that in the future, 1 in 4 of us is likely to die of cancer, but we are also likely to survive for at least 5 years post-diagnosis. The point that Elvira made most strongly was that compliance is equivalent to a commitment to build trust. She stressed that compliance programmes will fail if the cultural underpinning is not there. She also stated that effective programmes need to include continuous improvement practices.

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[1] http://www.internationalpharmacongress.com/

[2] http://pharmacomplianceforum.org/

[3] Gabor Danielfy was a leading figure in Compliance within life science companies, and a founder member of the organising committee for these conferences before his untimely death in November 2011. He is honorary Chairman of ETHICS.

The second Keynote Address of the conference was given by Marc le Menestrel, PhD, who is visiting professor of Ethics at INSEAD and associate professor at University Pompeu Fabra, Barcelona. The title of his address was "Business Ethics for Pharma and Device Companies" and he took us on a thought-provoking journey through the principles of ethics in business. Marc encouraged us to look at ethics, not as polar opposites of ethical or unethical behaviour, but as a continuum with various shades between behaviour that is wholly ethical or wholly unethical. He also encouraged us to think about how UNethical we all are, as most people believe themselves to be more ethical than those around them, which clearly cannot always be true. He reminded us that being compliant is not necessarily the same as being ethical; we can be compliant and unethical at the same time. Marc views the idea that the rational role of business is to maximise profit (as espoused by Milton Friedman in 1970) as a tragedy. I found Marc's ideas sufficiently stimulating that I looked up some of his published papers following the conference[4] where I found further interesting concepts about the rationality (or otherwise) of ethical decisions.

The penultimate session of day 1 was a roundtable on "Integrating ethics theory into ethics practice" moderated by Dominique Laymand, a conference co-chair. This session began with a presentation from Dan Ostergaard, CEO of Integrity by Design, who emphasised the need for companies to reward the types of behaviour they want their employees to exhibit. He also talked about the "sweet spot" where what is ethical, what is legal, and what is compliant overlap.

The first day of the conference concluded with a detailed look at the Spanish market by a distinguished panel representing healthcare authorities, HCPs, patient groups, and industry bodies. The panel was ably moderated by José Zamarriego Izquierdo of FARMAINDUSTRIA, and centred on a discussion of the importance of collaboration between the different stakeholders when developing and enforcing policies and procedures. In this case, the various stakeholders include all the groups represented on the panel and others. This is a critical point for success, not just between external stakeholders, but also between internal stakeholders within organisations.

Day two began with a Keynote Address from Huguette Labelle of Transparency International, who opened by stating that the world has high expectations of our industry because of the life and death nature of illness. She also stated that almost 2 billion people do not have access to medicines. As a citizen of the Western world, and given a global population of around 7 billion humans, I found this number quite shocking. Huguette split her talk into three main sections, discussing the key topics around corruption, the environment (in the sense of the business and public climate, rather than global climate change), and an "ethical package". I found many of the statistics used during her discussion unhelpful because they did not always attribute a source, or define whether the figures were global or local, and if local then to where. However, the main thrust of what she said on corruption was that it costs healthcare systems lots of money globally, which roughly translates to avoidable suffering and loss of human life in many of the poorest countries in the world. Dr. Labelle's discussion on the changing environment focused around public demands for greater transparency, rapidly changing legal and regulatory frameworks, and the need to tackle the huge increase in counterfeit and sub-standard medicines and medical devices. Her discussion of an "ethical package" gave a vision of companies putting integrity before profits in a world where CEOs will talk and lead by example, and they will see Compliance Officers as their "best friends". Huguette also talked about the RESIST programme[5] developed by the United Nations Global Compact and others, which she recommended as a good tool to help Compliance Officers combat many different forms of corruption. She concluded by making several recommendations to the industry:

[4] http://www.insead.edu/facultyresearch/faculty/profiles/mlemenestrel/
[5] http://www.unglobalcompact.org/docs/issues_doc/Anti-Corruption/RESIST.pdf

- Gain independent assurance (e.g. from consultancy firms) of the effectiveness of compliance programmes to build greater credibility
- Work with local communities to listen to their issues and correct them
- Include third parties in Code of Conduct training and at least get their commitment that they will not pay bribes
- Publish the locations and names of all subsidiaries
- Work together as a sector to exchange training programmes, codes, and information about problem areas, e.g. companies can get together (without breaking antitrust laws) to talk to local authorities to correct problems, including offering help to fix them as other industries have done.

The next session was an Anticorruption Roundtable, which followed on well from Dr. Labelle's discussion of global corruption in our industry. Vivian Robinson began this roundtable by talking about the lack of major prosecutions resulting from the introduction of the UK Bribery Act. He was not surprised that there have not yet been any major prosecutions because these cases necessarily take time to bring to court, the UK Bribery Act only applies to cases that have occurred since 1st July 2011 (i.e. it is not retroactive), and the UK's Serious Fraud Office is limiting the pool of cases to the most serious ones because others can prosecute less serious cases. He went on to talk about the potential for future rewards for whistle blowers being introduced in the UK along the lines of the *qui tam* provisions in the USA. Joe Tompkins talked about the joint US Department of Justice and Securities & Exchange Commission guidance on the US Foreign Corrupt Practices Act that was published in late 2012. He emphasised the continued focus on individuals and extra-territorial matters whereby any link with the USA, such as a letter passing through the US postal service, can be used as a trigger for involvement in a case. Later, Joe talked about the Ralph Lauren case from April 2013[6], which led to the first Non-Prosecution Agreement in US history as a direct result of their timely, voluntary and complete disclosure to, and cooperation with, the relevant authorities. Peter Dieners talked about authorities across Europe implementing better cooperation between, say, the tax authorities and local prosecutors to bring bribery cases to court. He also talked about a new focus on the effectiveness of compliance programmes, particularly following the introduction of new laws in Germany and similar laws about to be introduced in Spain. Lew Morris highlighted the key points of the "Obama Care" programme in the USA where the authorities have 30 new tools available to them to help combat corruption, such as data mining. Lew also discussed a trend for US authorities to hold line managers criminally accountable for the actions of their team members, even if they knew nothing of those activities.

The morning of day 2 concluded with an EU Transparency Roundtable including updates from Denmark, France, Netherlands, UK, and EFPIA. Reinforcement, or regaining, of trust is a common driver of transparency programmes across Europe, but the way in which these programmes are implemented differ widely between countries. In the Netherlands and the UK, the transparency programme has been driven by the industry with little or no involvement from the authorities. In Denmark, the Health Minister set up a working group in early 2012 to discuss possible regulations, and in France, a new local Sunshine Law has been passed to enforce disclosures of 2012 data by 23rd May 2013 (the day after this discussion). The new EFPIA Code requires aggregate and individual disclosures of 2015 data in 2016 for payments to healthcare professionals and healthcare organisations. EFPIA has asked local industry bodies to set local limits below which no disclosures will be required. All the panellists agreed that whilst transparency is important, it is also expensive.

[6] http://www.sec.gov/news/press/2013/2013-65-npa.pdf

The discussion concluded with a run through of results from the latest Global Transparency Management Survey organised by Cegedim.

The afternoon of day two was taken up with concurrent mini-summits on a variety of tempting topics, both local and global.

Day three began with Arthur Muratyan, General Secretary of ETHICS (see above), speaking passionately about the aim of ETHICS to be a reference society for compliance and ethics professionals in life science / healthcare companies that will provide a range of services, supporting them to develop and better manage their roles and duties. The association's activities will be based around the following four pillars:

- Communication
- Education and Professional Development
- Think Tank
- Networking / Sharing of Experience and Best Practices

Arthur also talked about the perfect storm of more compliance professionals being needed versus more of us leaving our roles due to stress or frustration and what ETHICS can do to help.

The final plenary session of the conference was a Roundtable on "Compliance as a Profession" moderated by Reinhard Angelmar of INSEAD. This was a great final session with the whole audience as it focused on practical steps that can be taken towards professional recognition and certification for Compliance Officers. Both Carl Coleman of Seton Hall University School of Law and Aditi Taylor of Deloitte outlined the various steps that other professions have taken on their journeys to becoming recognised as professionals. Whilst there were some overlaps in content between their presentations, they also had slightly different perspectives on how to move forward, which meant that the two presentations worked well together. Both agreed that having a society to develop training materials and a rigorous mechanism to examine competence, and to represent members' interests with external bodies are essential steps on the path to becoming a profession.

The conference concluded with the third set of concurrent mini summit sessions, again on a variety of topics, both global and local.

Pros and Cons of Attendance

Many organisations now provide conferences targeted at people in specific roles and it can be difficult to choose which (if any) to attend. When organisers make materials available such as comprehensive reviews of the whole conference, individual presentations, and videos of particular sessions to both attendees and non-attendees, you might think that you can get the whole benefit of attending without incurring the time and expense of travelling to these conferences.

Reasons not to attend conferences include the high costs of attendance, both for the admission fees and travel costs where conferences are held some distance away from your home base. You also need to be away from the office and your day job for the days of the conference, plus any travelling time needed to get there and back. These may seem like huge barriers, but they should be weighed against the benefits of attendance, including practical knowledge and guidance on specific topics. However, the most important reason to attend conferences is to network with your peers and develop a group of people to whom you can turn for practical help and guidance when you face a particular problem. If you have the right group of people in your network, they will also turn to you for help on particular topics, ensuring that mutual benefit is gained from the relationships.

I particularly like the annual international pharmaceutical compliance congress and best practices forum conference, and its American, Asian and Latin American sister conferences because the agenda is developed by compliance professionals who are doing these jobs and know what issues they face on a day-to-day basis. The organising committees for these conferences work together to develop great content that will really help people in compliance roles within companies, based on their knowledge and experience. They also have a good track record of sourcing high profile speakers from the industry, regulators, governments, prosecutors, and commentators on the industry (such as Transparency International). These conferences also attract sponsor and exhibitor organisations that can provide a wide range of services to support compliance professionals in their roles. Having all these organisations in one place within an exhibit hall is another benefit of these conferences, meaning that you spend less time searching for organisations that can help you to solve problems.

These factors combine to make conferences a great place to meet the right people who will be good for your network (on a mutually beneficial basis) in addition to providing great content that will have many practical applications in your day job.

There is a third way to gain the learning from some conferences without attending in person, which is to attend online with live streaming of plenary sessions. This is a good compromise for those who cannot afford the time or who have insufficient budget to attend the conference in person. However, it does not enable any networking to take place, which I believe is one of the major benefits of attending conferences.

Conclusion

It is possible to gain a lot from the content offered by conference organisers after conferences have taken place and / or to attend conferences online, but if at all possible, I would strongly recommend attendance in person to ensure that you gain the most from the networking opportunity. Where budgets are strained, it is possible to attend perhaps one conference every two years, but the best learning experience will occur with annual attendance where possible.

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Sue has been a Compliance Officer at all levels from single marketing company and European Compliance Officer for GlaxoSmithKline (GSK) to international VP for AstraZeneca (AZ). At GSK, Sue established the Risk Management and Compliance Board for the UK marketing company under the leadership of the UK Finance Director. As GSK's European Compliance Officer, she gained a reputation for a pragmatic approach by providing practical help and guidance to Marketing Company Presidents who were keen to manage their compliance risks effectively. As VP Compliance for AZ's International Sales and Marketing Organisation, Sue was responsible for ensuring compliance in every country in which AZ had commercial operations except the USA and Canada.

In January 2010, Sue established the management consultancy, Sue Egan Associates Limited, specialising in Corporate Governance, Compliance, Risk Management and Change Management. Sue works with clients in various sectors (life sciences companies, charities, a government agency, and other industries) to help them find innovative ways to conduct business ethically and sustainably.