

Review of the 1st Latin America Regulatory Compliance Congress and Best Practices Forum

Sao Paulo, Brazil, 2nd – 4th October 2012

The First Latin America Pharmaceutical and Medical Devices Regulatory Compliance Congress and Best Practices Forum in Sao Paulo, Brazil proved that, although the region still has a long way to go in catching up with other regions, the right people are determined to make a real difference.

All plenary sessions were simultaneously translated into English, Spanish and Portuguese so that participants in the room could choose to speak and to listen in the language with which they felt most comfortable. Break-out sessions were flagged as being in one of the three languages. This is really important because key points can often become lost in translation where the participant has a good grasp of the language, but perhaps not of specialist phrases, especially as these can evolve quite quickly.

Looking at the Transparency International Corruption Perception Index (CPI)¹ for the region reveals less of a gap between the highest and lowest scores than for Asia Pacific, but more of a gap than in Europe. However, with only one third of the countries in Latin America scoring above 5, there is obviously a lot of work still to be done in the region to fight bribery and corruption. Further evidence of this point can be seen in the recent Walmart Mexico case and the trial of 38 members of the Workers' Party of Brazil on corruption charges, during which at least 3 senior members have been found guilty of corruption.

Joaquin Duato, worldwide Chairman of pharmaceuticals for Johnson & Johnson, began his keynote speech by saying that he was "among friends with a common purpose". He challenged the audience to step back and ask how to connect business and compliance, before telling us that it is the way to build sustainable business. He said that the reward of compliance is trust, and that by doing more than the regulations require, we are given greater trust. He stated that the industry has a responsibility to shape the future, to make the right rules, and posed (and answered) some questions to the audience:

1. Does the region have unique cultural issues? There are a lot of cultural differences, but far more similarities in Latin America than other regions, so cultural differences was no excuse at all (in any region), and should not be a barrier to doing what is right.
2. How has the Walmart case affected all businesses? Those businesses that exhibit compliant behaviours will be the ones that survive. The perception of corruption in the minds of consumers will take years to change.
3. What is the tone from the top in each organisation, and how are the key messages deployed to affiliates in every country? This is a key area where Joaquin sees compliance officers and others being able to help their leadership to spread the right messages and to report back when those messages are not understood.

¹ For more information about Transparency International and their work, go to <http://www.transparency.org/>, or to view the 2011 Corruption Perceptions Index, go to <http://www.transparency.org/whatwedo/publications> and select the review. CPI scores are out of a maximum of 10 with scores of 5 and below indicating "a serious corruption problem". The highest score in the 2011 Index was 9.5, achieved by New Zealand.

4. Companies usually focus training, monitoring and controls internally, but what about partner organisations? Companies need to put some effort in to at least train their third party partners in the right behaviours, and to exercise the audit rights that are now more common in third party contracts.
5. What should we all be doing now to build the future trust? What the industry did 10 years ago seemed fine at the time, but with today's eyes, we see things differently. We need to look carefully at today's practices with tomorrow's eyes to anticipate what current practices might not be acceptable when viewed from the future.
6. Finally, he said that the passion, commitment and enthusiasm in the room for compliance was obvious, but how can we communicate this to others when we return to work after the conference? It begins with principles and conversations that help people to make the right decisions. We also need to reward the right behaviours and have a good sanctions system for when things go wrong.

I found that, like all keynote speakers at these events, Joaquin spoke from the heart and really understood what compliance officers need to help their companies to achieve, but he also understood the realities of the external environment and how the actions of a single player in a market can have an impact (either positive or negative) on all the other players in the market. The ripples from our actions are indeed wide and often run deep.

There were many other thought-provoking sessions during the conference, including the Latin America Roundtable, in which it was revealed that most countries in Latin America have two or more industry bodies to which companies are affiliated. Whilst it is not new to have separate industry bodies for medical devices, research-based pharmaceutical companies, and generics pharmaceutical companies, I find it difficult to understand why Mexico, for example, needs 13 industry bodies. I understand from discussions at the conference that work is being done to try to reduce this number. I wish those involved every success!

Among the usual (and necessary) worldwide updates, there were also some region-specific sessions, including the Spotlight on Mexico (in Spanish) and Spotlight on Brazil (in Portuguese) sessions that I was unable to attend due to my lack of language skills. It is important to spread knowledge of what is happening globally, but it is equally important to talk about specific issues for countries within the region, and the people who attended these two sessions spoke highly of learning a lot about what to look out for when they get back to the office.

On the final morning of the conference, there were three forward-looking and external-looking sessions, around communications and training, critical thinking, and the future of compliance in the region. It is vital to the success of compliance teams everywhere that they are able to attract and retain high calibre individuals into key roles within the function; they are the future of compliance. If we are to one day reach my dream of every employee being their own compliance officer (and there being no need for a separate compliance function), we need to ensure that our colleagues really understand what they need to do to be successful in a compliance manner. To achieve this, we need to ensure that we not only have the right people in compliance teams now, but that they are also well trained in both the mechanics of the role, and the "soft skills". These sessions were a step in the right direction to achieve this goal.

To find out more about the Pharmaceutical Compliance Forum (PCF), their website is www.pharmacomplianceforum.org. To find out more about the Latin America Pharmaceutical and Medical Devices Compliance and Best Practices Forum congress, including how to get copies of the congress presentations, the congress website is www.latinamericanpharmacongress.com.

Sue Egan MBA, Director, Sue Egan Associates Limited, Editor@SueEgan.co.uk



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.