

COMPLI... COMPLIMENTARY... COMPLIANCE... COMPLICATED!



WE LIVE IN A STRANGE WORLD WHERE GOVERNMENT'S POLICIES GET RATED BY PRIVATE AGENCIES AND WHERE PRIVATE INDUSTRY ACTORS ORGANISE THEIR OWN SELF ASSESSMENT IN ORDER TO REGULATE THEIR ENVIRONMENT DUE TO THE LACK OF GOVERNING LAWS. EVERYBODY GETS 'RATED' THOSE DAYS EITHER BY A TRIPLE A OR BY GREEN OR ORANGE LIGHTS! AND IT IS NO DIFFERENT IN OUR MEETINGS INDUSTRY, AND PROBABLY EVEN MORE SO IN THIS REGULATED ENVIRONMENT OF THE HEALTHCARE SECTOR.

When working with healthcare meetings, we have to take into account the local laws. Historically however, when it came to dealing with sponsors and exhibitors, we used to negotiate with the *marketing* departments, as they were heavily focused on achieving easy contact with their prescribers. Then, with the financial evolvement of the industry we were led to deal with *purchasing* departments, which we thought, was the nightmare of all! And then, a few years ago, the R&D departments came progressively into the loop as habits and various studies showed the real need of who the prescribers companies wanted to contact. Today, now, we have to deal with the *compliance* people in the Pharmaceutical (pharma) or Medical Devices companies (MD).

HOW AND WHY DID WE COME TO THAT?

Some people will say it's because of the various excessive attitudes of healthcare professionals (HCPs) and/or pharma and/or

MD companies offering, for example, complimentary skiing holidays to physicians or because of effective scandals or even because of the economic burden due to the bad state of many healthcare systems worldwide. In fact, compliance has always existed... it was or simply is.... a normal fact of life... a matter of normality! But it is now positioned in the centre of the 'game' because people want transparency; people want ethics; people want to be able to keep track on how things, processes and services are being provided.

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And when it comes to touch the life and health of humans, then transparency has a new face: 'Where does the drug I was prescribed, come from?'; 'Why did the doctor prescribe that one?'; 'How did the

pharma or MD company produce the drug or the device?'; 'Why is the cost so high?' etc. Things that were once in the hands of an elite minority are now in the hands of everyone!

RULES, REGULATIONS AND LAWS

The rules are the ones edicted by the companies themselves; they can be pharma or device companies. They have their own rules. For instance, for some of them, no invitations anymore to HCPs to meetings and events - this has to be respected to the letter.

Then there are regulations; those that are edicted by the professional unions or associations of pharma or device companies. For some of them, they are only recommendations (although many understand them to be compulsory); for others, they are in any event compulsory and non-compliance of members to those regulations will inevitably lead to a ban. Regulations are also edicted by the European Union.

As Europe is not a country in its own right, we cannot call them 'laws' but, in practice as well as in theory, they should be followed by all country members. Regulations are usually very strict: they impose restrictions in order to be as ethical as possible. For example: 'no use of a "resort" city or venue for a congress', but the understanding of this is not really clear as this kind of wording easily leads to misinterpretation. Too often the word 'reasonable' is a key word in many articles, the reason being; of course, that these are recommendations and thus cannot lead to any discrimination.

Furthermore, there is indeed a website which gives 'green or orange lights' to meetings the basis of which is sometimes obscure to calculate.

Finally, and probably more importantly, there are the laws, which by their very interpretation say that there is no other way than to follow them. Whilst in the USA, the law may apply to the whole country, in Europe, comprising a number of countries, it is seen differently: the laws per country apply and may be different, stronger and more complicated than European regulations or other company rules.

The sunshine act in the USA has been held as an 'example' for many other countries, especially in Europe; as a start, the UK has the Anti-Bribery Law and France recently voted the 'Loi sur le Médicament' ('medicine law').

The laws are very strict and geared by a main keyword in the mind of all legislators: 'transparency'. If HCPs are receiving grants, invitations, gifts, etc., these need to be officially declared via various means: an official website being the most common solution by governmental bodies, like the 'agency' in France or a subsidiary of the FDA in the USA. It is however not always clear who has to complete the declaration (also called 'Conflict of Interest') which changes according to the country: in the USA, it is by the HCPs themselves; in France, it should be by the inviting companies. The law in the USA for instance is very strict and some Pharma companies have been subject to huge penalties even exceeding 600 million dollars!

HERE, NOW AND FOREVER

So, compliance is not a joke, it is not even a passade; those who think it is just a bad moment to go through are wrong.

This is how our world, at least in the healthcare sector of the meetings industry it is now. Do not expect to have it changed, count compliance as, in your everyday life, you have to count ethics, good behaviour and honesty.

However, we must not forget one thing: congresses are, if not the best, one of the best possibilities offered to HCPs for Continuing Medical Education and if compliance leads to ban or destroy this educational tool, who and how will governments pay for this indispensable training?... Not only would this impoverish the entire healthcare sector but also the whole meetings industry will be in trouble!

This article was provided by the International Association of Professional Congress Organisers, author Philippe Fournier, President MCI France and Immediate Past President of IAPCO. IAPCO represents today more than 115 professional organisers, meeting planners and managers of international and national congresses, conventions and special events from 41 countries. info@iapco.org / www.iapco.org

