

## Edoardo Lazzarini Wins Prestigious Award



We announce with great pleasure that ETHICS member Edoardo Lazzarini was presented with the [2015 PwC Award for Leadership in the Advancement of Ethics in the MedTech Industry](#) at the Global MedTech Compliance Conference in Athens in May 2015.

Here is an extract from the award speech:

“There is much to say about this year’s recipient of the annual leadership award; however, a constant theme underscored in the nominations and in speaking with those who have personally worked with him, is his passion for Compliance. Not only in the way that he constantly strives for a better understanding of the importance of Compliance, but also through his collaborative, innovative and visionary work within his Company and industry groups. ... Known for being “refreshingly outspoken” and a “highly engaged promoter of a high performance Compliance culture”, he has supported important Compliance initiatives such as the Conference Vetting System of Eucomed and the Ethical Med Tech Logo project. ... With pleasure, we present this year’s annual Compliance Leadership award to Biomet’s EMEA Compliance Officer, Edoardo Lazzarini.”

Congratulations, Edoardo! We are very pleased to congratulate you on being given this prestigious award.

# News from the Medtech Conference in Athens



by Enno Behrendt

In May 2015, roughly 280 Compliance Professionals of medical technology companies gathered in Athens for our annual conference. The agenda, presentations and pictures can be found [here](#). For our Society's newsletter, I would like to share some thoughts on the two overarching topics:

1. We have to face the fact that our self-regulation has not been successful.

Our efforts to establish an effective set of rules for our interactions with Healthcare Professionals have received attention and maybe even applause, but have ultimately not kept lawmakers in many countries from issuing laws that regulate the same area.

There is an immediate challenge with this: Unfortunately, the new laws tend to be un-harmonized and also tend to focus on administrative solutions like data disclosure and registration. That is good news for software-vendors. The lobby booths in Athens were dominated by companies that sell tools for transparency and event-management, because for Life Science companies of all sizes, fulfilling the new laws' requirements efficiently is currently the focus topic.

But it is bad news for us Compliance Professionals, because what the new laws don't do is to actually provide better assurance for the interactions between the industry and HCPs. To this day, Compliance Professionals around the world still mostly have to rely on the meagre and meandering interpretations of "appropriateness" when advising their companies, and all Compliance Professionals and Business Managers I spoke to were pretty sure that the new laws will not have an anti-corruption impact proportionate to the administrative costs.

Still, we will have to make sure that the new laws are adhered to. That leads to a longer-term challenge: It's even harder now to differentiate between what we do because it's good and sustainable business (this is the pre-eminent and most successful "tone from the top" theme), and what we do because the laws require us to do it. The risk of us Compliance Professionals becoming merely "the transparency guys" is obvious and not to be underestimated – if we look from our business colleagues' perspective, they probably have seen us communicating more about transparency laws and database collection than about any other topic in the past years.

This will probably be a defining challenge for our profession for quite some time: Ensuring efficient administration of particular laws without neglecting overall anti-corruption effectiveness.

2. But there is good news to this as well.

Fortunately, the new laws are getting doctors and their associations more involved. In Athens, one afternoon was devoted to the Healthcare Professionals viewpoints. Several quite high-profile panellists explained their perspectives and showed that clearly, there is a growing awareness among Healthcare Professionals about how much more complex the regulations have become, and that this is in no way a challenge for Industry alone.

This is very encouraging, and we should make good use of it. Customers have a major, if not the biggest possible impact on anti-corruption efforts, and the better we can communicate to them how we are "doing Compliance", the easier and non-disruptive it will be to act on our guidelines.

It will require some soul-searching: Also in Athens, somewhat of an "us-versus-them" thinking was hard to deny, sometimes quite publicly from the questions raised to the HCP panellists. For some of our profession, it might be new that doctors are now in the audience and are listening closely. But for all of us, this should be a welcome and immensely helpful development.

# News from the Pharmaceutical Conference in Brussels



by Sue Egan

The 9<sup>th</sup> International Pharmaceutical Compliance Congress and Best Practices Forum was held in Brussels 11-13 May. It was lovely to see so many ETHICS members both attending and speaking at the conference. It was also good to have so many enquiries about membership and we have welcomed several new members since the conference.

For the second time, EFPIA organised a free Stakeholder Workshop on the first morning. This year, the agenda included sessions on Clinical Trial Transparency, Working with Patient Organisations, and several different perspectives on Transparency / Disclosure.

I found the talk by Robert Barrington of Transparency International (TI) to be thought-provoking in parts. He began by giving us the usual global spend figures (in \$) on bribes in our industry, the % of total spend, and the impact on people's lives in the poorer countries. These figures are available to download from the [Transparency International website](#). What was new about this talk (for me) was that TI is considering producing an industry index for the Life Sciences industry which would encompass Pharmaceuticals, Biotechnology and Devices companies. This would work in a similar way to the existing Defence Industry Index which puts companies into bands A – F, where A is "good" and F is "bad". The rating is based on two separate scores taken from internal data and external data. Only 4 companies worldwide are in band A for the defence industry, while there are more than 100 in band F. I wonder where our companies will sit if a Life Sciences Index is developed in the future? What can we, as Compliance Officers, do to help our companies to get into band A rather than band F?

The Global Chief Compliance Officer Roundtable that followed the TI keynote address gave great insights into these challenging roles. The nuggets that most appealed to me were:

1. Writing policies does **not** change culture;
2. People do as their managers do;
3. Companies will never have enough compliance team members to control everything - we need to create the right environment so that we can rely on people to do the right thing;
4. Compliance is becoming a global function on a par with HR and Finance in many companies, instead of being a transient function formed to resolve a particular problem and dissolved once that initial problem has been resolved.

An interesting session early on day 2 was the roundtable entitled "The New Marketplace: The Purchasers Perspective". This session brought together practising Healthcare Professionals, payers, and others involved in provision of healthcare services. As you might expect in a discussion among professionals with different perspectives on healthcare provision, there was some disagreement with at least one person stating that "the patient has feeble role to play" while others thought that patients drive (or should drive) their own treatments. One participant suggested that healthcare provision should focus on POOs (Patient-Oriented Outcomes) instead of DOOs (Disease-Oriented Outcomes). Whatever your perspective, it is a big step in the right direction to get more people from the various aspects of healthcare provision involved in these conferences.

Marc de Garidel, Chairman and CEO of Ipsen, gave the keynote address on day 2. He talked about three main topics:

1. The changing geographical footprint for the industry – in the past, the USA dominated the industry globally, but by 2018 emerging markets will be close to 30% of global healthcare spending, led by China.
2. Innovation – from 2000-2010 the industry doubled its R&D effort without translation into drug approvals, which led economists to question the long-term viability of the industry. However, since 2010, the industry has been increasing innovation such that 2014 saw the highest number of drug approvals in a single year. One third of these were incremental improvements, but a further third were treatments for previously untreated conditions. This increase in innovation is affecting the whole life sciences sector, not just pharmaceutical.

3. Regulation – since the 2008 financial crisis governments have had less money for innovation and many have increased regulation. Europe is moving towards greater harmonisation of regulation. In USA, the FDA has now accepted that some drugs can be approved following limited phase I & II trials. Europe launched [IMI](#) (Innovative Medicines Initiative) in 2008 as a public-private partnership between the European Union and EFPIA to “speed up the development of better and safer medicines for patients”. One of IMI’s projects is looking at ways to demonstrate the value of drugs.

Marc concluded by saying that the industry depends on trust and transparency for its future and the role of the Compliance Officer is key for developing and improving trust.

Much of the discussion during the breaks was on transparency-related topics. Given that reporting requirements are already active in several countries, including France and Portugal, and the first reports are due to be published under the EFPIA Transparency Code early next year, this should come as no surprise.

Transparency is an interesting topic, not least because of the variety of approaches that companies are taking. During the discussions, I came across four broad approaches:

1. Develop an in-house solution that, at least partially, integrates with existing payments and expenses systems and generates reports in the format of the templates provided.
2. Use spreadsheets to capture key information off-line and then “send” the information to Word reports for final checking before generating the PDF.
3. Outsource the entire solution to a software and / or data vendor who will implement a standard package to take data from existing systems and generate standard reports. This approach usually requires data to be extracted from existing systems, which may or may not be included in the price.
4. Some smaller companies that are not members of any of the EFPIA-affiliated industry body associations have decided not to participate in transparency activities except where these are mandated by local laws. In these cases, they tend to favour approach 2 above, especially as they tend to have a manageable number of transactions per country per reporting period.

Whichever approach your company is taking to managing transparency requirements, if work has not yet begun, there is definitely a lot of catching up to be done!

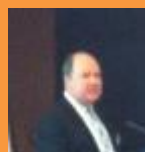
The conference concluded with a session on “Crafting the Compliance Programme of the Future”. My favourite thoughts from this session include:

1. Implementing the [seven elements](#) is no longer enough – the external environment is more demanding and Compliance Officers must be part of the decision-making at all levels; post-approval checking is not enough.
2. Compliance Officers need a good support network (both internally and externally) to help them succeed – this is one area where your ETHICS membership can help (take a look at the list of members in the Members’ Space). 😊
3. It is relatively easy for Compliance Officers to gain technical skills (e.g. by rotating on audits), but it takes more effort to learn leadership skills; people need to be given opportunities for development in different geographies and directorates (e.g. R&D, manufacturing, commercial).
4. A new CEO wanted to meet the Global Compliance Officer as one of his first discussions; this would not have been the case 10-15 years ago and demonstrates the great leaps forward for our profession.

Overall, I came away from the conference feeling invigorated and refreshed having met lots of old friends and new colleagues, and learned a lot.

## Work Stream Update: Educational Partnerships

by Dave O’Shaughnessy



This work stream was initiated after the General Assembly in Paris in October 2014 and the members are Anne Beasley, Isaure Kergall, Dominique Laymand, Stephen Nguyen Duc, and Roeland van Aelst, with Dave O’Shaughnessy leading.

ETHICS continues to be very supportive of numerous educational events, conferences, and courses that help in the education, training, and development of compliance professionals. We have been very active in the first half of 2015 including extensive participation in the IPCAA workshop in Zurich in March, the International Pharma Compliance Congress in Brussels in May, during which we supported multiple sessions, and the Eucomed conference in Athens in May. We also continue our important support and engagement with Seton Hall / Sciences Po (Certificate in European Healthcare Compliance Ethics & Regulation) and INSEAD programs. Many of these are familiar to most of you and we are continuing work to compile our participation to allow members to see which ones we actively support and to allow you to consider which ones may offer opportunities to grow your compliance knowledge and experience. Our support is often very visible with ETHICS sponsorship and support clearly referenced in conference programs etc. We would like to publish an initial overview in the second half of 2015 or review in the General Assembly.

This work stream will also help to facilitate reviews with the Strategic Committee to optimise the contribution and participation of ETHICS members aligned with the principles of our association, and to look to assess new opportunities for enhancing our view of valuable events that complement the activities of ETHICS. We would also welcome input on any other activities our members may have supported through other invitations and to determine if these may be beneficial to add to ones that we commit to supporting year on year. These could be local events, universities etc. that you may support or some other emerging events which you found to be well organised and engaging.

To achieve this, the work stream continues to compile a list of support work and confirm the leads or regular contributors, as well as the principles underpinning this support. We will give a further overview at the 2015 General Assembly and aim to be better at tracking this support in advance, seek and act upon any feedback received with the organisation supported, and review the feedback within ETHICS.

Whilst we continue to receive general positive feedback, we will also look more closely at how ETHICS supports ongoing standards for courses so that our contribution improves year on year. This area needs more attention in the second half of 2015 and would also benefit from further discussion at the General Assembly.

**We welcome any further views on areas this work-stream could usefully focus on. Please do get in touch with your ideas.**

## Work Stream Update: Compliance Professional Competency Model

You may remember from our previous newsletters that this work stream team (Eva Gardyan-Eisenlohr, Andreas Gascard, Katalin Pungor and Tamara Tubin with help from Sue Egan) was asked to design a simple and pragmatic way to identify and develop the core competencies of a Compliance Professional. We began by developing a "Vision and Mission" and "Strategic Pillars", which led us to a clear foundation: it's about individual skills, profiles and attributes which describe the behaviours of effective Compliance Professionals, rather than just their responsibilities. In a workshop we applied our insights to the Korn Ferry Competency Leadership Architect® (based on the 'Lominger Model') model to identify core competencies for Compliance executives, managers and specialists.

The team recommended that ETHICS should come to an acceptable mutual agreement with Korn Ferry to enable us to use the profiles that we have developed using their Competency Leadership Architect® materials. Unfortunately, Korn Ferry wanted too much money to grant a licence to use their materials with our members, so we have decided to try a different approach.

Following the success of our workshop last year (where we developed the model that we wanted to share with members), we have planned another workshop in late July 2015 to develop our own competency profiles model based on our extensive reading on this topic and what we have seen working well in companies. We hope to have a practical approach defined in time for the Q3 newsletter. Watch this space!

## Work Stream Update: Sharing Best Practices

Our work stream members are Cécile Gousset and Piergiorgio Pepe. We aim to share best practices on topics linked, in particular, to education and training, rather than reinventing the wheel. As long as these best practices work well, have no intellectual property or confidentiality issues, and are not commercially sensitive from a competition law perspective, we can share them for customisation by each member.

Thanks to the generosity of individuals, companies, industry body associations and law firms, we have now added almost 30 items to our [Best Practice Sharing](#) page on the ETHICS website. We hope that you have found (or will find) these materials useful.

Because training and education is an important pillar of a compliance program, this work stream will enable us to build a databank of documents and initiatives, in different formats, where all ETHICS members can go for inspiration.

The process for proposing material and ideas can be accessed via the [Members' Space](#) of our website so that every member can contribute to the Best Practices Sharing databank.

You will need to [login](#) to the website to gain access to these materials. If you have forgotten your login details, please send an email to Sue Egan via [contact@ethicspros.com](mailto:contact@ethicspros.com) or [ethics@sueegan.co.uk](mailto:ethics@sueegan.co.uk).

**This work stream can live only through the contribution of all ETHICS members, so we count on you!**

## Closing Remarks

As you can see, we have worked hard to improve your overall experience during the first half of 2015. However, **we still need your help**. If you would like to join a current work stream, propose a new one, or have any feedback for us that would help us to provide better services to our members, please do **get in touch** via email to [contact@ethicspros.com](mailto:contact@ethicspros.com), or to any member of our Strategic Committee.

### **ETHICS Strategic Committee**

(Ann Beasley, Pierre Dupourque, Suzanne Durdevic, Jacques Fontas, Eva Gardyan-Eisenlohr, Cecile Gousset, Thomas Hauser, Isaure Kergall, Dominique Laymand, Arthur Muratyan, Anthony McQuillan, Stephen Nguyen Duc, Dave O'Shaughnessy, Pascale Paimbault, Teresa Rico, Tamara Tubin, Roeland van Aelst).

## Upcoming Events in 2015

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|-----------------------------------|---|
| <b>17 – 18 August</b>             | Asia Pacific Pharmaceutical Compliance Congress and Best Practices Forum, Manila, Philippines   |
| <b>15 September – 17 November</b> | Online course on “Unethical Decision Making in Organizations” presented via <a href="#">Coursera</a> by Guido Palazzo who spoke at the 2014 ETHICS General Assembly |
| <b>21 – 23 October</b>            | Pharmaceutical Compliance Congress and Best Practices Forum, Washington, USA  |
| <b>16 – 19 November</b>           | Seton Hall Law School and Sciences Po European Healthcare Compliance Certification Programme, Paris   |
| <b>23 – 24 November</b>           | <b>ETHICS General Assembly (24 November), Clifford Chance Offices at 1, rue d’Astorg, 75008, Paris and pre-dinner on 23 November</b>                                |
| <b>30 November – 04 December</b>  | INSEAD Healthcare Compliance Implementation Leadership Programme Part II: Managing and Enhancing the Effective Compliance Programme                                 |