

Introduction

By Roeland van Aelst, ETHICS Board Member

Dear Member,

A newsletter is an ambitious undertaking, it is often easy to start and fill the first issue. It requires however devotion, persistence and passion to keep it going. An association like ETHICS cannot really exist without it. Just have a look at the 4 pillars that form our foundation; Communication, Education and Professional Development, Think Tank, Networking/Sharing of Experiences and Best Practices. A Newsletter fits these purposes like a glove, as a perfect addition to the General Assembly Meeting and the upgraded website. You will see that through this letter we will meet several of those founding principles. We will be able to reach you more often and at the same time it gives you the opportunity to share your experience, knowledge and wisdom with your fellow members.

While this Newsletter is there for you, at the same time, it can only be made by you. It is and should always be an instrument of exchange. So we call upon you to generously submit articles, ideas, practices, knowledge and whatever you can think of, that you believe can contribute to further develop our members and our profession in general. The more you give the more you will get, and not just for this Newsletter. Feel free to propose topics for the General Assembly Meeting or to contribute to one of the work streams. As you will learn in this first issue of 2016, a lot of work has already been done by passionate members that deserve a warm round of applause for the results achieved. Practice is the best school, so through the work of this team you now have access to a wealth of materials that will surely grow moving forward. The competency model, that is now readily available, can really help you to be a better professional.

Further you will find the contributions of experienced members on what is there to do beyond the 7 elements of a good compliance program, or what can be expected in terms of further scrutiny on corruption, like in France.

I will however not close this opening remark without offering my thanks to the members of all the work streams and a special thanks to Stephen for organising the General Assembly pretty much on his own.

Enjoy the reading!

Update from ETHICS 2015 General Assembly

The 2015 General Assembly received good reviews at the time and we have recently sent out a feedback survey to all our members and guests who attended.

Your feedback is an important factor in helping us to improve our member services, so please do complete the survey, which can be found here: <https://www.surveymonkey.co.uk/r/9BPGMPT>.

The presentations from the 2015 General Assembly can be found within the secure members' area of our website [here](#). You will need to be logged in to access these presentations – see below for more information.

Going Beyond the “Seven Elements”

by Abdul Luheshi, ETHICS member

The 9th Pharmaceutical Compliance Congress held in Brussels in May 2015 included a session entitled “Crafting the Compliance Program of the Future”. During this session three key points were put forward:

1. Programs need to go beyond the ‘seven elements’¹,
2. Compliance Officers need to be effectively networked, and
3. Compliance professionals need to broaden their skill base.

In this article, I would like to offer some thoughts around the first point: what is meant by ‘going beyond the seven elements’ and what role should the Compliance professional play in making this happen?

Over the past 10-15 years we have witnessed the emergence of compliance (in this context primarily anti-bribery / anti-corruption (ABAC) compliance) as a function within most, if not all, healthcare companies. This drive has been led by the pharmaceutical sector, but medical device and other associated participants soon followed the same route. Broadly speaking compliance programs were established around the ‘seven elements of an effective compliance program’ and/or the US Sentencing Guidelines². The approaches employed generally had common themes:

1. The Law Department / external counsel played a significant role to ensure compliance with national and international laws and regulations;
2. A Code of Conduct set the internal standards;
3. Standard Operating Procedures operationalised the policies and standards.

These steps are necessary and form the foundation for any compliance effort – especially where companies are starting from nothing. However, and at the risk of being contentious, compliance programs which focus primarily or solely on the ‘seven elements’ have proven to be of limited effectiveness in keeping employees, managers and Boards safe from regulatory risks. A core reason behind this limitation is the challenge of affecting a change in people’s behaviours. Employees who take the wrong decision often do so with the full knowledge of their organisation’s policies and procedures. Why?

A lot of research has been (and continues to be) done in this area. Simply put: why do good people make bad decisions? Here are a few factors to consider:

- **Leadership and authority** play a fundamental role. Ask yourself these questions:
 - How does the head of the organisation relate to the issue of regulatory compliance (which should encompass all regulations not merely ABAC)?
 - How do they position it in relation to other priorities for the organisation?
 - What status do they afford to the heads of their compliance organisations?
 - Do they consider themselves accountable for behaviour in their TOTAL organisation?
 - Do they demonstrate the type of behaviours that set the right example for their organisations?
- **Company culture** (which may have differences across different parts of an organisation) has a major impact on the context that employees work within. A common feature in many of the recent corporate scandals is the presence of a culture of aggressive competition often compounded by lack of trust and a sense of fear.
- **Targets** are key drivers in decision-making. In large corporations it is not unusual to encounter targets which are centrally set and are overly stretching in a local context. In addition, what is the process involved and the level of input that local management (and employees) have in target-setting?
- **Performance assessment and incentives** are fundamental to what people will and will not do. Consider the following questions:
 - What are the metrics used to determine performance?
 - How well is the process followed by line-managers throughout the organisation?
 - How is success celebrated and failure managed?
 - What are the rewards on offer?
 - Is it a case of ‘winner takes all’?
 - Would a sales representative lose a disproportionate amount of his or her income if they don’t ‘make the numbers’?
 - How much effort is put into assessing ‘the *HOW*’ compared to ‘the *WHAT*’?

Compliance professionals are far too frequently kept away from considering such broad topics. Sometimes the weight of routine responsibilities simply gives us no opportunity to even think about how any of the above factors impact on the success or otherwise of their programs.

However, as compliance programs mature and with them management's perception of the role of the compliance function, compliance professionals have the opportunity to move to the next level. Here are some thoughts:

- Compliance professionals have to establish ourselves as equals within the organisation. The Chief Compliance Officer should have a 'seat at the table' and be involved in the decision-making process for the broad organisation.
- Leaders must actively engage their compliance teams and consider them as key partners. On the flip side, compliance professionals must become fluent in how businesses work and be at ease with acting as a 'wise counsellor' or 'trusted advisor' within the management team.
- Compliance functions must challenge the existing procedures and routines and drive towards process simplification. Accountability must reside with line managers and not the Compliance Officer.
- Compliance leaders must be major agents of change. They need the awareness and sensitivity to identify structural issues (e.g. incentive plans) and support their colleagues and the organisation's leaders in making appropriate changes. This is particularly critical where cultural aspects impede the presence of a 'culture of ethics'.

¹ The 'seven elements' refers to The Seven Elements of an Effective Compliance Program as defined by the Office of Inspector General (OIG) in 2003, which can be found [here](#). Even though it has been defined by a US government agency, it contains good advice for companies operating in any country.

² The US Sentencing Guidelines are non-binding rules that set out a uniform sentencing policy for defendants convicted in the United States federal court system, which can be found [here](#).

How to get the most value from the Members' Area of the ETHICS Website

by Sue Egan

You probably already know that the Members' Area of the ETHICS website is only accessible to our members, but you may not know what is available to us.

During 2015, only 65% of members accessed the Members' Area at all, and of those who did access the Members' Area around one third accessed it only once.

On a brighter note, around one third of those who logged in to the Members' Area did so more than five times. These members have obviously seen some value in logging in. Perhaps you can too.

The Members' Area Welcome page contains links to the following useful information:

- Members' Best Practice Sharing – this page includes lots of useful materials for members to use internally within their companies and not for profitable purposes – see below for more information);
- Members Directory – we currently display the name and email address for every member so that members can get in touch with each other, although in future we may share more information; there is a search function that enables members to find each other, for example by looking for all or part of a company name, all or part of their first name, all or part of the city or country where they are based;
- Update your personal profile where you can update your password, email address, telephone numbers, address, role and company – it is important to keep your contact email address up to date as we mostly communicate with our members via email;
- General Assembly presentations from previous General Assemblies, including a summary of the speaker presentations at each General Assembly – this is especially useful for new members who want to know what they missed and members who want to remember a particular point mentioned by one of our speakers;
- Newsletters – this section contains links to our previous members' newsletters for your information;
- Membership Fees Payment page – this page enables you to pay your annual membership fee via PayPal; the alternative method is to pay directly from your bank account to the ETHICS bank account including your name as the payment reference.

If you have forgotten your login details, you can email me at ethics@SueEgan.co.uk and I will trigger an automated reset of your password for you.

When you log in and see what information is available, if you have any feedback to make it better for everyone, please do let me know using the same email address.

I will be hosting a webinar session soon to help members to get the most out of the website. If you would like to join the webinar, or you have a particular question that you would like to be addressed, please do let me know.

Work Stream Update: Compliance Professional Competency Model

The members of this work stream (Tamara Tubin, Andy Gascard, Katalin Pungor and Eva Gardyan-Eisenlohr with support from Sue Egan) have now completed the major task of developing a competency profile model for Healthcare Compliance Officers.

The Competency Model has been reviewed and approved by the ETHICS Bureau, and has now been added to the members' area of website [here](#). Note that you will need to be logged in to see the Competency Model – see above for more information.

There are two next steps for this team:

1. Host a webinar session to launch the new Competency Model to members
2. Develop a self-assessment tool that members can use to identify their gaps for action

One or two people, which may include an academic, will be added to the existing team members to take this important work forward to the next step. This team will also link up with the Curriculum team to ensure that suitable development opportunities are available to help members to fill the gaps

Look out for your invitation to join the webinar in the near future.

Work Stream Update: Sharing Best Practices

The members of this work stream (Cécile Gousset, Piergiorgio Pepe and Ingrid Callies with support from Sue Egan) have devised a process for review of materials offered by members and others for sharing within the members' area of our website. They have also reviewed all the materials that are now posted there (and some others that did not make it).

To see the materials, click [here](#) (you will need to be logged in to see these materials – see above for more information).

This team is now actively seeking your input to the best practice sharing area of the ETHICS website.

If you have any materials in use within your company that could be shared within ETHICS, or if you know of any materials that you would like us to request permission to publish within the members' area of our website, please reach out to this team with your suggestions. The process for sharing materials can be accessed [here](#).

Evolution of Anti-Corruption Laws in France By Arthur Muratyan, ETHICS Secretary General

France has, for some time, been criticized for its poor enforcement of anti-corruption laws. Even though it was an early signatory to the 1997 OECD (Organisation for Economic Co-operation and Development) Convention on Combating Bribery of Foreign Public Officials in International Business Transactions, the number of cases brought to French courts has remain very limited.

A new Anti-bribery law will be soon discussed at the French Parliament.

The bill at issue will be introduced by the French Finance Ministry, Michel Sapin. It will establish, under the joint authority of Finance and Justice Ministries, a new Anti-Corruption enforcement Agency, named "Agence Nationale de Prévention and Détection de la Corruption" (*National Agency for the Prevention and Detection of Corruption*).

This Agency will replace the existing SCPC ("Service Central de Prévention de la Corruption" or *Central Service for Prevention of Corruption*) and will have more extended powers to conduct inquiries and investigations on alleged facts of corruption.

The most important innovation brought by the proposed law would be a new procedure offering companies that are suspected of corruption the possibility to settle their case with the public prosecutor.

Companies, in a process comparable to what already exists in the US, would have the possibility to cooperate and negotiate a guilty plea arrangement through which they may avoid heavy litigation that could be damaging to their reputation.

The fine (which would be made public) would be "proportionate to the advantages gained from the laws' violations" and represent a maximum of 30% of the company's average turnover of the last three years.

In addition, the company would be monitored by the new Agency for a three-year period to ensure that it adequately establishes or reinforces its compliance and anti-corruption programmes and trainings.

The new law would also contain other important elements, such as some rules regarding the legal protections extended to whistle blowers.

It should represent an important development for compliance professionals on which ETHICS Association will keep you informed.

Closing Remarks

The end of Q4 2015 and the beginning of Q1 2016 have already been very busy with lots of developments for Compliance Officers, both internally and externally. Within ETHICS, the Bureau and Board are planning several new initiatives for 2016, including a deontological code for members. Planning is also under way for our 2016 General Assembly (see upcoming dates below).

If there are **any topics that you would like to be included in the 2016 General Assembly, a newsletter, a webinar, or materials placed in the members' area of our website**, or you would like to volunteer to write any materials, please do get in touch with Sue Egan at ethics@SueEgan.co.uk to let us know which topics are of interest to you.

Thank you all for your continued support of ETHICS; together we will be able to achieve even more in 2016 than in previous years.

Upcoming Dates in 2016

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| 07 – 09 March | IPCAA (International Pharmaceutical Congress Advisory Association) Congress , Hilton, Copenhagen Airport, Denmark |
| 01 April | Deadline for receipt of applications for Gabor Danielfy Scholarship to attend the June session of the Seton Hall / Sciences Po European Healthcare Compliance Certification |
| 10 – 12 May | International Pharmaceutical Compliance Congress and Best Practices Forum , Hilton Convention Centre, Warsaw, Poland |
| 06 – 09 June | Seton Hall Law School and Sciences Po European Healthcare Compliance Certification Programme , Paris, France |
| 27 June – 01 July | INSEAD Healthcare Compliance Implementation Leadership Programme Part I: Managing and Enhancing the Effective Compliance Programme |
| 29-30 September | The 2016 ETHICS General Assembly will be held on the afternoon of 29 September and all day 30 September at the Clifford Chance Offices at 1, rue d'Astorg, 75008, Paris. Dinner will also be arranged for 29 September. |