General Assembly Meeting Notes

Thursday 26th September 2013

Clifford Chance Offices, 10 Upper Bank Street, London, E14 5JJ

Welcome speech: Dominique Laymand, ETHICS Chairman of the Board

Dominique opened the meeting by expressing her pleasure at the number of ETHICS members attending the meeting in London. She reminded the audience of the Society's origins with a small number of Ethics and Compliance Officers from pharmaceutical, biotechnology and devices companies meeting irregularly to discuss key issues of the day. This began several years ago and one person who was key to the success of these early meetings and who had a bigger vision for a society to be formed was Gabor Danielfy. Dominique expressed her regret that Gabor's untimely death meant that he did not see the Society that he had dreamed of being formed although he has been named posthumously as ETHICS' honorary Chairman. Dominique was pleased to welcome Gabor's daughter, Ananda, to the morning session of the General Assembly to represent him and to see the results of the work that her father helped to initiate.

Morning agenda introduction: Roeland van Aelst, ETHICS Board Member

Roeland introduced the busy morning agenda, consisting of both administrative elements and tangible progress reports from the work streams. He expressed his thanks to all members of the work streams for their hard work and progress to date. He also invited as many members as possible to actively participate in the presentations and to offer their expertise and practical support to the work streams following the General Assembly meeting.

Administrative and Legal aspects: Pascale Paimbault, ETHICS Treasurer and Arthur Muratyan, ETHICS Secretary General

Arthur gave a brief overview of the Society's history, aims and structure before moving on to discuss the highlights from the last year. Arthur expressed his thanks on behalf of the Society to Clifford Chance for their valued support, including provision of offices for this meeting.

Pascale then presented the Society's financial update. She began by setting out the purpose of presenting financial information before showing the positive results of her management of the members' money. The figures presented were actuals for 2012, budget for 2013 and forecast for 2014; they showed year-end balances of almost 23k for 2012, just over 13k for 2013, and just over 16k for 2014 (all figures rounded to the nearest thousand Euros). The figures take into account lower income from memberships in 2013 than 2013 because some members joined late in 2012 and were given extra months of membership for no charge, and an increase in revenue from memberships in 2014 compared with 2012. Pascale also

broke down the membership numbers into the different companies for both 2012 and 2013 to show the spread of support that the Society enjoys.

Arthur then went through the resolutions and asked the members present to vote on each resolution. All were agreed unanimously.

Compliance Benchmark Survey: Peter Dieners then went through the survey that Clifford Chance had conducted during April and May 2013, and invited discussion from the audience. The findings presented are based on the 102 responses received from pharmaceutical (around 40%) and medical devices companies (around 60%). The discussion following Peter's presentation generated lots of suggestions to ensure that the survey is even better next year, including a suggestion to ask EFPIA, EUCOMED and others to participate in future.

Work Stream Sessions: representatives from each work stream gave the highlights of the work done so far and invited suggestions and offers of help from the members. All the work streams have made good progress and all requested further help to enable them to make even more progress in the coming months.

One of the major achievements of the **value of transparency** work stream to date is the useful spreadsheet summarising the transparency reporting requirements across Europe, which can be found in the Members' Area of the ETHICS website. Note that this team also requested volunteers to keep the information up to date as things change, so **if you are able to volunteer to do this for one or more countries, please do get in touch with any member of this work stream**. The presentation describes the 3 main elements of this work stream (personal and professional leadership development, training and education, and tools to raise business ethics awareness); lists the 5 team members (Kalisa Barratt, Marion Beller, Pierre Duporqué, Jacques Fontas, and Pascale Paimbault); and gives a "call to arms" to members to get involved if they have ideas on what this stream should be doing, including offers of help where appropriate. The discussion following the presentation confirmed that members are likely to gain lots of value from the transparency reporting reference spreadsheet and agreed with the work stream members that having a sounding board of members and others to test their ideas on would be beneficial.

The tool kit team's presentation sets out the objectives of the work stream; opportunities for members to get more involved (**please do offer to help if you have time and relevant expertise**); ground rules for sharing; and a summary of each of the three main tool kit categories (training and education, personal and professional leadership, and raising business awareness). This work stream needs good examples from members who are willing and able to share their work more broadly. Because compliance is being recognised as a source of competitive advantage for companies, it is important that members who do share their examples have the relevant permission from their companies to do so, and that all members respect the spirit of sharing within the Society whilst respecting anti-trust / anti-competition laws. This work stream has, therefore, devised a set of ground rules for sharing (see slide 6). Each presenting member of this team then talked the audience through the examples that they had gathered from within their companies to showcase the types of examples they are looking for from members. The members of this workstream are: Andreas (Andy) Gascard, Tamara Tubin, Cécile Gousset, Katalin Pungor, Laura Nassar, Dumitru Uta, Ingrid Callies, and Heidi Buergi (who is currently on an extended work assignment).

The continuing education work stream engaged the audience in a discussion of the options they had explored including issues around definitions of a curriculum for compliance officers (i.e. what does an effective compliance officer need to know and what skills should they have), difficulties involved in accreditation, ensuring the right quality of tuition, and absence from commercial bias. The discussion demonstrated that there is still some work to do for this work stream. **Again, if you are able to offer practical support, please do offer to help.** Members of this workstream are: Dominique Laymand, Roeland van Aelst, Ann Beasley Bacon, Maria Teresa Rico, and Eva Gardyan-Eisenlohr.

A set of questions has been devised for members to pose to their HR colleagues, which are:

- Is there an ideal profile for a compliance professional in your opinion? If so, what attributes would you include? Is there a preferred background?
- How do you see the career path developing for compliance professionals?
- How can we ensure that compliance is perceived as a business enabler for compliant growth / competitive advantage?
- How can HR support their colleagues working in compliance to enable compliant business growth?

All members are requested to ask these questions and send the responses to the Strategic Committee by email to ethics@sueegan.co.uk by **close of business (your local time) on 13th December** 2013.

Afternoon agenda introduction: Ann Bacon, ETHICS Board Member

Ann introduced the afternoon speakers, all of whom are external to the Society, and who had each been chosen to complement their fellow speakers and offer members different perspectives on the work that we all do.

Roundtable: External Ethics and Compliance Perspective 1 - Healthcare Providers

Moderators: Thomas Hauser and Tamara Tubin

Healthcare Providers: Mr. Konstanty Radziwill, VP Polish Chamber of Physicians and Dentists and President of CPME; and Prof. Dr. Med. Wolfhart Puhl, specialist in Orthopaedics, Orthopaedic surgery and physical & rehabilitative medicine, Emeritus University Ulm.

Thomas and Tamara set the scene for this round table by looking at some recent press reports of inappropriate interactions with healthcare professionals that reinforce public perceptions of an industry behaving unethically. The invited HCPs were invited to share their views of the industry and what needs to be done to improve the industry's image.

Both highlighted the need for good education for HCPs, and Prof. Puhl asked how this education should be paid for: should tax-payers' money be used, should the HCPs pay, or should the industry pay? Prof. Puhl went on to say that HCPs have to trust that the products will do what they are supposed to do because they have no opportunity to challenge this, so they rely completely on the specialists within the industry to give them the right information at the right time to enable them to do a good job for the patient. Thus, education is key to helping HCPs support patients. He also

suggested that harmonisation of the provision of education for HCPs across Europe (including funding) would be helpful, but realised that this probably needs to be taken up by politicians.

Mr. Radziwill stated that meetings should be "problem oriented" rather than "product oriented", labelled as educational (with appropriate accreditation), and with the right HCPs invited to move the industry away from the unethical image of companies simply trying to promote their own products regardless of need or effectiveness. Mr. Radziwill also highlighted the need for transparency of relationships, especially sources of funding and affiliations, although he believes that the vision of relationships between HCPs and the industry that originated in the USA with the Sunshine Act is not the ideal direction as it treats both as suspects in wrong-doing rather than as partners who work together for patient benefit.

Roundtable: Business Ethics

Moderators: Peter Dieners and Vincent Nys

Speakers: Professor Dr. habil. Josef Wieland, Scientific Director of the Konstanz Institute of Value Management with research interests in business ethics, applied ethics, and social ethics; and Prof. Carl Coleman, specialist in the legal, ethical, and public policy implications of medical treatment, research and public health, Seton Hall Law School.

Peter and Vincent introduced the members of this panel as highlighting the need for cultural awareness within companies, especially when trying to encourage ethical behaviour.

Prof. Coleman said that ethics is about doing things. He stressed that whilst the intention is relevant, it is really about behaviour. He also stated that the overlap between unethical and illegal behaviour is incomplete in that some behaviour can be unethical without being illegal and vice versa. His slides contain an interesting diagram of the different types of ethics.

Prof. Wieland said that an effective system needs more than paper: it also needs leadership, integrity and ethics to build a values-driven compliance management programme. He also said that just having training and policies means nothing without effective implementation programmes. He asked what we will do if China develops an extra-territorial law like America's FCPA (Foreign Corrupt Practices Act) or the UK's Bribery Act and wants to enforce its views on the rest of the world? He also talked about diversity, sources of good behaviour and whether or not bonus systems are aligned with compliance values.

The audience discussion focused on cultural matters such as the whistleblower in Mexico who was asked to leave the company whilst the wrong-doer was promoted, or Sweden having the highest number of complaints against EUCOMED-affiliated companies with around 1/3 of them being self-reported whilst other countries have had no reported complaints ever. When asked what can be done about culture, Prof. Wieland responded that culture is surmountable so nothing can be done. Prof. Coleman stated that part of the difficulty lies in understanding what the culture is because process measures are easier to

devise than cultural measures: he suggested that ETHICS might work with an anthropologist to help work through some potential cultural measures.

Roundtable: External Ethics and Compliance Perspective 2 – Third Parties

Moderator: Dave O'Shaughnessy

Third Party CROs: Dr. Douglas Peddicord, Executive Director of ACRO (Association of Clinical Research Organizations) with policy expertise in the conduct and regulatory oversight of clinical trials; and Dr. John Poland, Senior Director, Regulatory Policy, Covance UK clinical development services

Dave introduced Doug and John as both representing third parties operating on behalf of the industry and as key participants within the industry who gain insights from their close working relationships with HCPs that are of use to members' companies.

Doug stated that the CRO objective is two-fold:

- To protect humans, and
- To protect the scientific process

He also said that ACRO had campaigned against the inclusion of scientific process payments in the US Sunshine Act because there is a relatively low risk of corrupting the scientific process. He was disappointed at ACRO's lack of success in their bid to keep it out of Sunshine.

John stated that the business of CROs is running clinical trials, so they must comply with GCP (Good Clinical Practices). Because the Sunshine Acts in the USA and France are legal requirements, CROs must also comply with them. These requirements and those of EFPIA and local industry associations have had a large impact on CROs, not least because many companies are now moving towards closer relationships with fewer CROS. These new partnerships are deeper than previous ways of working, and they rely on a positive two-way flow of information.

Dave asked how CROs apply Fair Market Value principles for payments made by CROs on behalf of companies (commonly called "pass through" payments). Doug replied that the view of the past was that companies passed the risk to the CRO, whereas the current view is much more of a shared risk.

A member asked if it was better to use the CRO's SOPs (Standard Operating Procedures), or the client's SOPs, to which the response was that using the CRO's SOPs reduces risk because their staff members are used to working with their internal SOPs. If every client required the CRO's staff members to use the client's SOPs, then staff would soon become confused, thus increasing the risk of non-compliance.

A discussion of standardisation of data formats followed from the previous discussion: every client has their own format for data which increases complexity and so the risk of mistakes also increases. With 8 ACRO members accounting for around 16% of the CRO market and around one thousand CROs in total, Doug thought it likely that many of the smaller CROs would not be able to keep up with the changing requirements.

The discussion concluded with Dave's observation that R&D organisations are not building compliance functions to the same extent that commercial organisations are. For example, there is

usually no country-level support for CROs from the client company's R&D organisation as there would be in the commercial organisation.

Conclusion from ETHICS Board Members Ann Bacon and Roeland van Aelst

Closing remarks: Dominique Laymand, ETHICS Chairman of the Board

Ann, Roeland and Dominique thanked all the presenters and those who had worked behind the scenes to make the General Assembly such a successful day, their fellow Board Members, Strategic Committee Members and the Society's general members for attending and participating so actively. In particular, Peter and Olivier of Clifford Chance were thanked for all their support to date.

They concluded that much progress has been made in the last year and members have much to look forward to in the next year.

These notes have been written by Sue Egan and represent her personal experience of the ETHICS General Assembly meeting 2013. If you notice any mistakes, please do let Sue know by email at Ethics@SueEgan.co.uk.

If any member who attended the General Assembly 2013 would like to receive a certificate of attendance signed by the Society's President, please send an email request to Sue Egan at Ethics@SueEgan.co.uk. Your scanned certificate will be emailed back to you as soon as possible.