IPCAA | International Pharmaceutical Congress Advisory Association

7th IPCAA Annual Seminar on Compliance 2018 - *in association with ETHICS*

March 20 and March 21 Radisson Blu Berlin

Medical Education and Scientific Exchange - Navigating the Complexity together!

Seminar highlights

Around 100 people met for the latest in the series of highly successful annual compliance seminars organised by IPCAA in collaboration with ETHICS. Yet again there was a programme crammed with learning, insights and opportunities to network and exchange on the evolution of the effects of compliance codes on meetings and medical education. 'Navigating the Complexities Together' was an entirely appropriate theme as Pharma and MedTech, Medical Associations and PCOs, Code Bodies and venue representatives met for a multidisciplinary open and frank exploration of current practicalities and future opportunities.

Practical Exchange – A New Approach

A new format practical exchange session was introduced this year and was well received by delegates, both those with little compliance knowledge and also those well-versed in the topic. Groups worked through the practicalities of mini scenarios based on real life situations. A group of experienced conference and compliance professionals were on hand to contribute their expertise in small group discussions and with all participants. Topics covered included the question of what compliance related topics to include in a congress planning meeting, sponsorship packages and sponsored items, satellite symposium arrangements, disclosure of transfers of value, delegate sponsorship and, of course, venue and location acceptability. Both Pharma and MedTech perspectives were covered.

All-in-all these case-based discussions proved to be an excellent way to learn and share practical experiences.

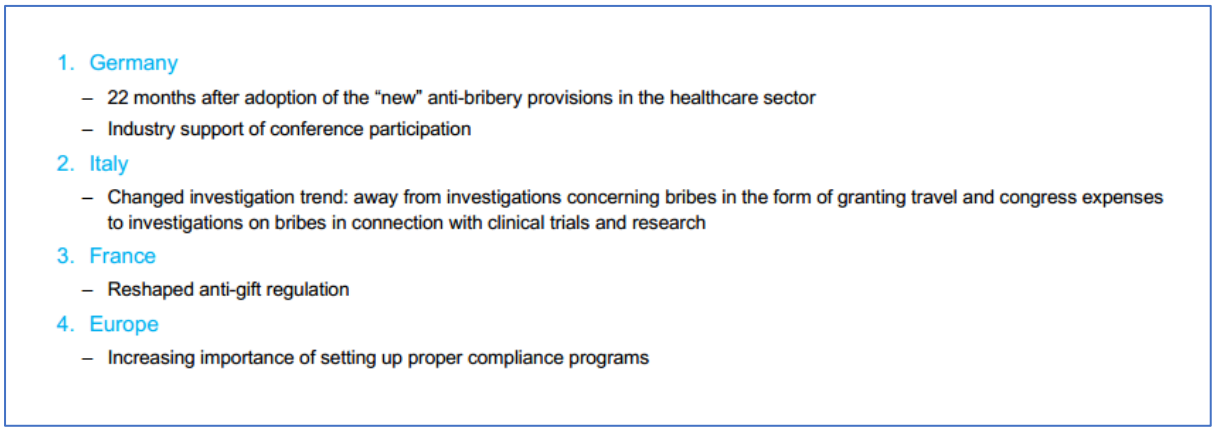
The main seminar – An important IPCAA - ETHICS collaboration

Christian-Claus Roth (IPCAA Co-President) and Arthur Muratyan (ETHICS Secretary General) opened the main seminar introducing their respective associations. They stressed the importance of the collaboration between IPCAA, whose mission is to ensure the most beneficial outcome for all parties involved in medical congresses, and ETHICS being the independent international association for healthcare compliance professionals.

The Legal Perspective: Recent developments in anti-corruption regulations across Europe.

The anti-bribery and corruption legislation scene continues to evolve at apace across Europe. Attendees were familiarised with the latest developments by Ann-Kristin Cahnbley from the law firm Clifford Chance. She focussed on recent developments in Italy, Germany and France and also made some general observations on Europe as a whole.

Some European Compliance Headlines



Visual from Ann-Kristin Cahnbley, Clifford Chance.

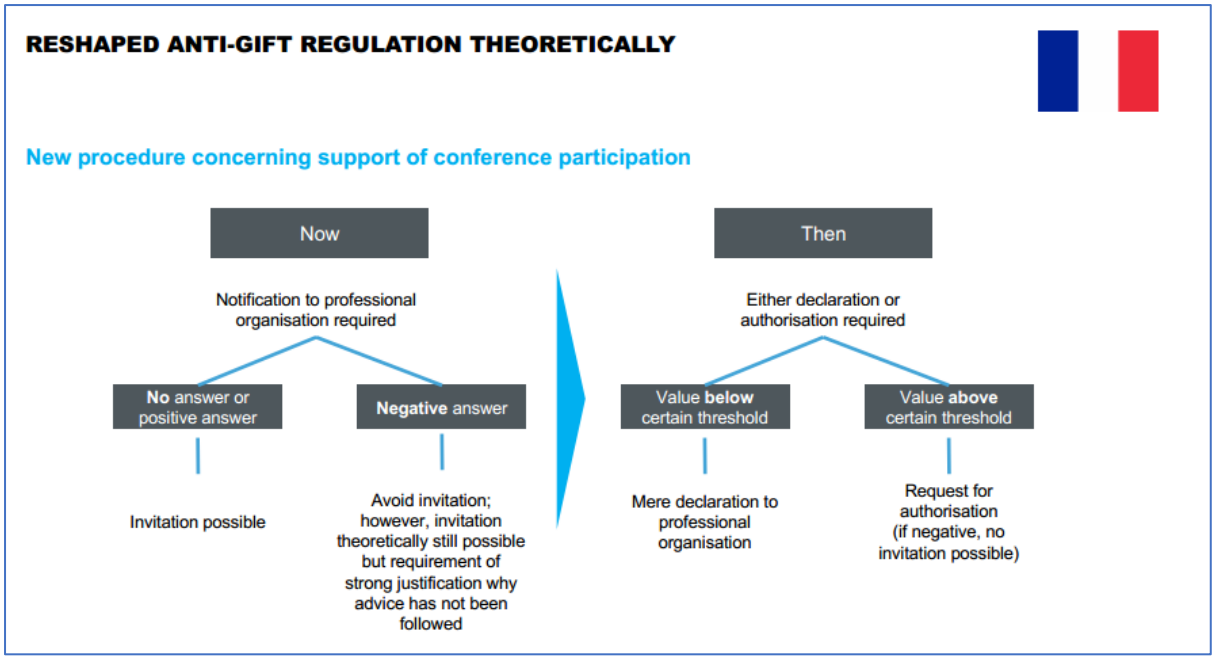
Germany: The new German law on corruption in the healthcare sector, introduced in June 2016, covered for the first time not just physicians also other HCPs including private practitioners. It prohibits the granting of any benefits to HCPs in order to be preferred in an unfair manner. Currently there are some investigations but, so far, no convictions under the new law. The main area of investigations has been the 'Aut-idem' situation which allows substitution of a cheaper alternative if a box is not ticked. A case involves 2 physicians who crossed aut-idem box hundreds of times.

The German Law recognises the importance of codes and compliance with those codes can be seen as an indication of lawful cooperation.

The physicians' professional code and the law allow company support for conference participation although the trend is that more and more physicians want to pay for themselves and some companies are refraining from supporting passive participation in third party conferences. The Bremen medical association is notable because it sets limits for reasonable travel, accommodation and hospitality expenses.

Italy: The compliance focus is away from gifts and hospitality to clinical trial transparency. In particular, grants made available by companies for (sham) research activities have been considered as bribes. A new law requires the Italian government to adopt, within 12 months, several pieces of legislation in order to bring the national framework on clinical trials of pharmaceuticals up to European standards.

France: The anti-gift legislation affecting those manufacturing or marketing health products or providing 'health benefits' has been amended and will come into force by July 2018. The scope of covered persons has been expanded to include e.g. medical students, osteopaths, chiropractors or psychotherapists, who were not mentioned in the previous legislation. It also covers societies – not just individuals. A new derogation is being introduced which permits benefits in kind or in cash to be provided E.g.: remuneration, compensation of research activities (if proportionate to the service rendered), donations (in order to exclusively finance research/scientific assessment activities), donations to associations, hospitality (if reasonable and limited to the purpose of the event)



Visual from Ann-Kristin Cahnbley, Clifford Chance

Europe generally: There is an increasing importance of setting up proper compliance programs in companies. Some countries (e.g. France) have legal obligation to set up such a compliance program. There is a risk of large fines if management commits bribery or violates its supervisory duties (e.g. Germany) or, as in Italy, a Company cannot be held liable, provided it proves that it has established a proper compliance program.

Let's look at some specific codes

A recurring challenge for compliance in international meetings is that while individual national and healthcare sector codes all apply the same fundamental principles, when it comes to practical application there can be important differences between those individual codes.

With that in mind, the seminar examined a selection of important codes and explored the day to day practicalities of applying them. The German, UK and Danish Pharma codes and the MedTech Europe code were put under the magnifying glass. So, just how do we follow these codes?

Germany

Holger Diener, Managing Director of FSA, which is the EFPIA member association for Germany, gave insight into the German situation. FSA membership cover over 75% of the total turnover of prescription-only products in Germany and can impose fines up to Euro 400,000. Money raised goes to charity. Applying transparency rules is another important aspect of FSA activity. Transfers of Value in connection with Training Events must be disclosed.

In Germany the Doctor's association required transparency of sponsorship even before the EFPIA disclosure code came into effect.

Bringing the meeting up to date Holger commented that there have been issues concerning meetings being licensed so that a PCO is the commercial owner while a medical association is the scientific owner. This is apparently in order that the large amounts of money associated with congresses do not have to be declared as a transfer of value from a healthcare company a medical association. A compromise has now been reached whereby declaration jointly cites the

PCO and the Medical Association. Hospitality and venue choice must be acceptable whether offered by PCO or a Medical Association. Congresses may still have hospitality evenings, but it should not be mentioned in pre-conference material. Even so, there are still some concerns with PCOs organising conferences in luxury venues.

UK

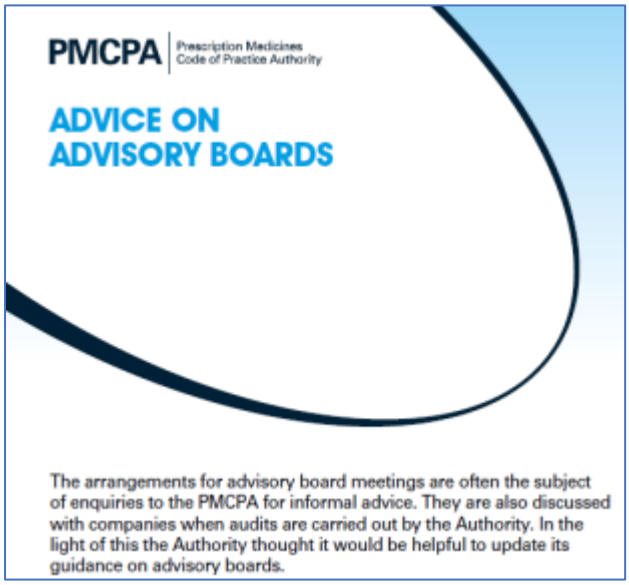
Anne Erwin of Innovative Compliance & Ethics Ltd is also a consultant to the PMCPA (Prescription Medicines Code of Practice Authority) which administers the UK Pharma 'ABPI Code of Practice'. She outlined some key relevant points of the UK compliance environment for meetings and congresses.

The Code very largely reflects the law but provides more detail. There are important 'Memorandums of understanding' between the PMCPA and the MHRA (regulatory authority) & the SFO (Serious Fraud Office) which outline how the government's and the Pharma Industry's regulatory responsibilities can be undertaken effectively alongside each other.

One particularly important Clause from the Code is Clause 2. A Clause 2 breach is considered to be particularly serious.

Anne also drew attention to Clause 3 which states that companies must not promote prior to the grant of the marketing authorization and that promotion must be in accordance with marketing authorization and must not be inconsistent with summary of product characteristics. This is particularly relevant to congresses where information about research will be presented and PMCPA has produced guidance, available on their website, which helps interpret that clause. There is also the requirement to declare sponsorship in papers relating to meetings and in published proceedings – and that declaration must be 'sufficiently prominent'.

Company Advisory Boards have come under the spotlight in recent years, including coverage in the national press. Genuine advisory boards are permitted but they must not be an excuse for other, eg, promotional, activities. This can be a difficult area to navigate and, again, the PMCPA have produced helpful guidance available on their website.



Visual from Anne Erwin / PMCPA

Denmark

Rikke Bækgaard Thomassen is Head of Secretariat and Legal Investigator at ENLI, Denmark's Ethical Committee for the Pharmaceutical Industry. 80% of the Danish market covered by ENLI.

The Pharmaceutical Industry in Denmark can still provide sponsorship for HCP participation in Professional events organized by a third party e.g. international congresses. However, in 1 of the 5 Danish regions that run hospitals HCP sponsorship has not been allowed. Rikke revealed though that within the last week an agreement between the regions and Danish Pharma has been reached.

All meetings, ads, etc. must be notified to ENLI and around 45% are reviewed. Only a very small number, 0.9%, result in a sanction or fine so we can conclude that Danish Pharma is very compliant.

There is a total prohibition against organizing entertainment with respect to pharmaceutical companies' own events (both in Denmark and abroad).

When sponsoring an event, a distinction is drawn between primary and secondary 'entertainment'. Primary entertainment would for example be music or other acts forming part of a stand-alone performance during a dinner or the like. Secondary entertainment is activities not consisting of a special event, which is limited in its extent and does not hold any entertainment value of significance in itself for the participant, e.g.background music, etc., at an opening reception or in a lobby.

Events including primary entertainment cannot be supported by pharmaceutical companies.However, pharmaceutical companies are permitted to provide sponsorship for HCPs attending professional events, if the (primary) entertainment associated with the event is expressly funded otherwise than by the pharmaceutical company's sponsorship, for example by attendees self-payment.

Also, venues for meetings must be acceptable; no 5-star hotels, unless there really is no alternative suitable venue and no gourmet restaurants. Beach hotels in summer are generally prohibited – although it could be argued that the weather in Denmark in summer is not always that great to make a beach venue desirable!

Importantly, the use of any sponsorship money should be clearly defined; unrestricted sponsorships are not allowed. So while payment of expenses to attend a scientific meeting is allowed an unrestricted grant that does not identify how it will be spent should be avoided.

ENLI has published a guide on international congresses: www.enli.dk

MedTech Europe

Ceren Aral Desnos, Interim Director of Legal and Compliance at MedTech Europe gave a timely update – the new MedTech Europe Code was introduced on January 1st 2018, so we now have the first indications of how it is working in practice. Headlines were the phasing out of direct sponsorship, a chapter on general criteria for events and transparency of educational grants. Companies can provide educational grants to hospitals, medical societies or funds to PCOs to support genuine medical education. These include educational grants provided to support HCP participation in Third Party Organised Events. Importantly HCP beneficiaries are selected by the receiver of the grant, not the healthcare company and individual recipients must not be disclosed to companies unless required by local legislation such as in France and Turkey.

The General criteria for acceptability of events still apply! Grants can only be provided to legal entities but never individuals and will require a written contract & other related documentation. Grants must be publicly disclosed by companies.

Find more information at www.ethicalmedtech.eu/resources

Panel discussion

The presenters were joined by Alesa Lehmann Ivancic from IPCAA and Stephen Nguyen Duc representing ETHICS with Christian-Claus Roth chairing.

Q: What if the HCP pays for an activity themselves which might breach a code

A: That could be OK.

Effect of GDRP on transparency is not yet clear.

Need to be visionary – what is the next 'transparency challenge'? Need astrategic approach. Maybe pricing issues will be the next big challenge?

Its important to keep focussed on the benefit to patients that comes from meeting attendance.

In some countries, hoping for more disclosure than HCPs are currently permitting

Q : How can HCP perception and expectations be changed?

A: A matter of time resistance is generally amongst the older HCPs.. Now there is more discussion in HCP circles

Number of conferences with issues is decreasing

Q: What can cos do to enhance understanding?

A: Rule books are dry and uninteresting. Case based training is a good

Move from compliance rules to a general integrity approach – a principled based approach is good but detailed applications can vary between players

EthicalMedTech has training for PCOs as well as member companies

Compliance can be especially difficult for small companies

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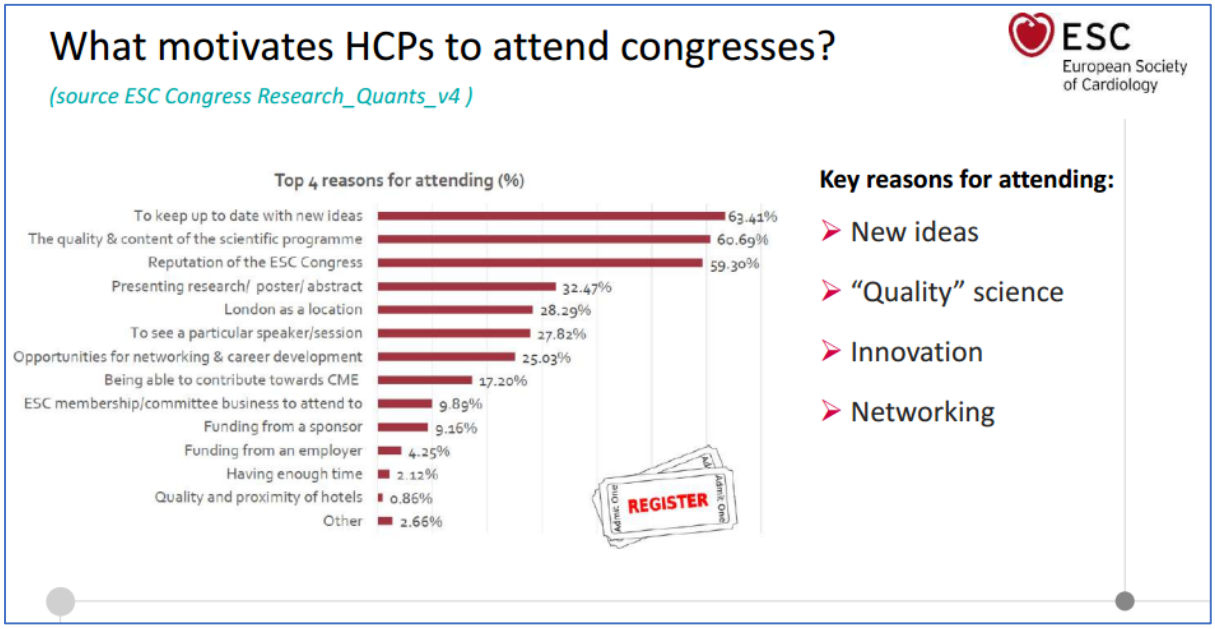
Codes in Action: How Medical Societies see the challenges – and how can collaboration be improved?

How to ensure high quality scientific exchange in this regulatory world?

Isabel Bardinet, CEO of the European Society of Cardiology, tackled this question from the viewpoint of a medical society. She commented that societies understand and very much go along with some regulations – but there are some (or at least their interpretations) that are worthy of review.

> Are there still societal benefits in doctors meeting & discussing scientific innovations, applications for practice?
> Are there still societal benefits in industry partners meeting with doctors to discuss innovations & applications of product in practice?
>
> The answer is most definitely YES



Visual from Isabel Bardinet, ESC.

Colleagues from around 145 countries come to a typical ESC congress. Congresses are seen as the best way to learn, to network and have professional exchanges and to test issues with colleagues.

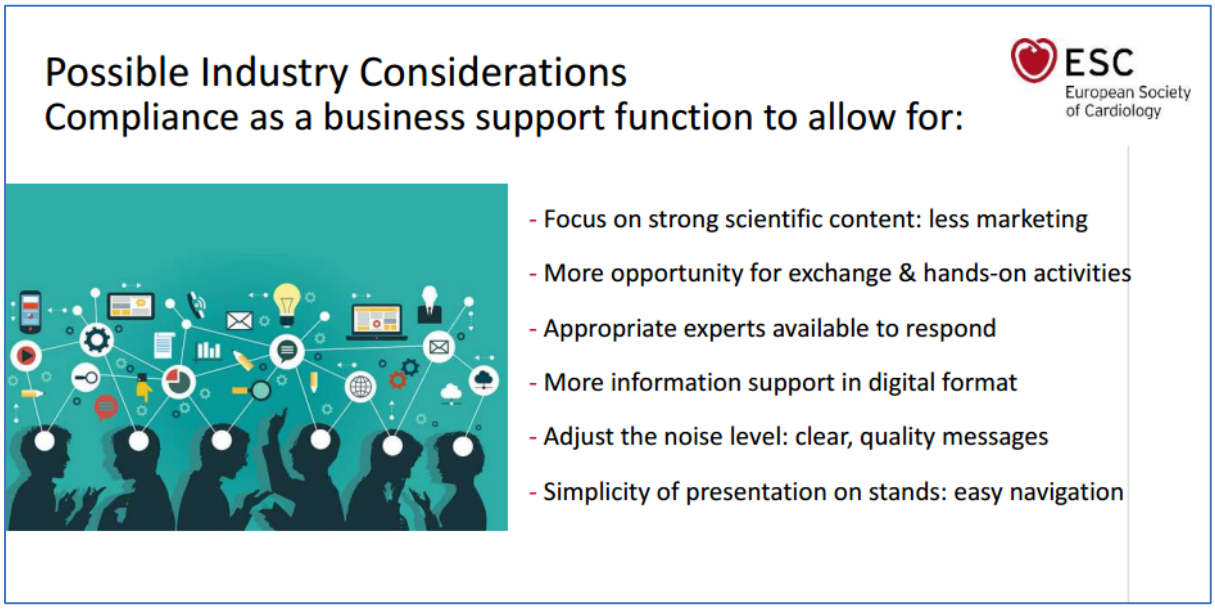
From an ESC survey, the scientific content at conferences was considered unique in its breadth and depth bringing enormous benefit to HCPs. Note however that the quality and proximity of hotels is at the bottom of the list of aspects that motivate HCPs to attend – and catering is not very important.

Congresses have developed and fundamentally changed. It was suggested that some industry partners may not have yet fully adapted to the changes. There is a question whether the regulatory framework is sufficiently nimble to allow the breadth of content that participants want – e.g. patient participation.

Networking is a key aspect of congresses and includes interacting with industry on topics such as the latest clinical trial results. Although the majority of delegates visit the exhibition hall there

must be a question about whether the industry exhibition space is still worthwhile and appropriate. Companies could rethink booths to better satisfy the delegates' desire to learn and have a scientific exchange.

Isabel stated that Congresses remain a very relevant & unique platform for learning & exchange of strong, independent scientific content. They serve medical societies mission, supporting healthcare professionals in delivering better care & reducing the burden of disease. She ventured some suggestions for industry.



Visual from Isabel Bardinet, ESC.

Some points to note about Congresses:

- Budgets continue to be a problem with the banning of direct delegate sponsorship by the Medtech sector with no alternative in place.
- In the future there will be more emphasis on personalised learning including content by age, country and speciality.
- Keep presentation of info simple as English is a second language for most delegates.
- Remember delegates from outside Europe come to European conferences e.g. Japanese can make up a significant proportion.
- Childcare provision is important. Over 70% of cardiologists are women and average age is 35 years. We need to allow them to come.

Panel Discussion

Isabel was joined by Steve Sealy, ERS, Jasper Bredesen, H. Lundbeck, Sophie Bricca, MedTech Europe and Juan Fuertes, PHA for the panel session chaired by Christian-Claus Roth.

Separation of commercial and medical can be important. But companies are not keen to take up this option when offered in the exhibition hall.

Patients go to booths to have a coffee! Access restrictions for patients to exhibition hall has not stopped me talking to industry people. Need to be clear on the purpose of the interaction but separation of booth areas not necessarily helpful

Scientific exchange is definitely the focus for doctors and Companies. If not science focussed, it's difficult to explain to public why industry pays for education. Journalists ask first 'what is the financial interaction of doc and co?

General public probably not very interested in the exhibition area – although societies and companies are concerned about reputation

Important to find areas where different players can cooperate in practice – and share that

Q: Could publicity from societies stress the positives of industry interactions?

A: Yes, could possibly do more promoting collaborations but the regulations don't help with that.

It's in the best interests of patients if they are sponsored to attend congresses . We need to work together on what really matters.

Codes in Practice: The positives and negatives of regulatory codes & how to develop better collaborations.

"So – you want to collaborate? ……. ". So started a very interesting talk from Steve Sealy ERS Associate Director. He reminded us of the purpose of the ERS – and other medical societies – which is to alleviate suffering and promote health through research, sharing knowledge and through medical and public education. ERS is a large, not for profit medical society with 35,000 individual and 70 national society members, and it has a worldwide reach. It undertakes a range of educational, scientific, publishing and advocacy activities. Although the Congress is extremely important to the society – the mission isn't to organise a Congress. When considering collaborations with Medical Societies it is important to take this into consideration. Medical societies are much more than an annual meeting.

In brief, their international congress attracts 22,000 delegates with around 500 educational sessions and training sessions. It includes a showcase of new diagnostics and therapies and a highly appreciated programme of Industry organised sessions. However Congresses are not just about attending sessions, they are the focal point of essential annual gatherings that facilitate a larger platform of activities relating to the advancement of medicine.

Visual from Steve Sealy, ERS

Whether we are collaborating around Congress or in relation to any other activities involving not for profit medical societies, Steve addressed three key questions:

- WHAT ARE OUR COMMON INTERESTS?
- WHAT ARE OUR DIFFERENCES?
- HOW DO WE BUILD GREAT COLLABORATIONS?

He suggested that there are several prerequisites for good collaborations. They should be built on understanding, respect and common goals with measurable outcomes. A clear, realistic approach linked to flexibility is needed. Oh…. and we need regulatory parameters that leave room for collaborations.

Codes and regs, whether created externally or internally, are there to advise companies and employees respectively, and in many ways they have brought welcome change. However, if the joint aim of the Industry, the medical societies and the regulators is to advance medicine through collaboration and ultimately improve patient care, some existing regulations are not supportive of collaborations and in some instances are hard to justify and simply present obstacles..

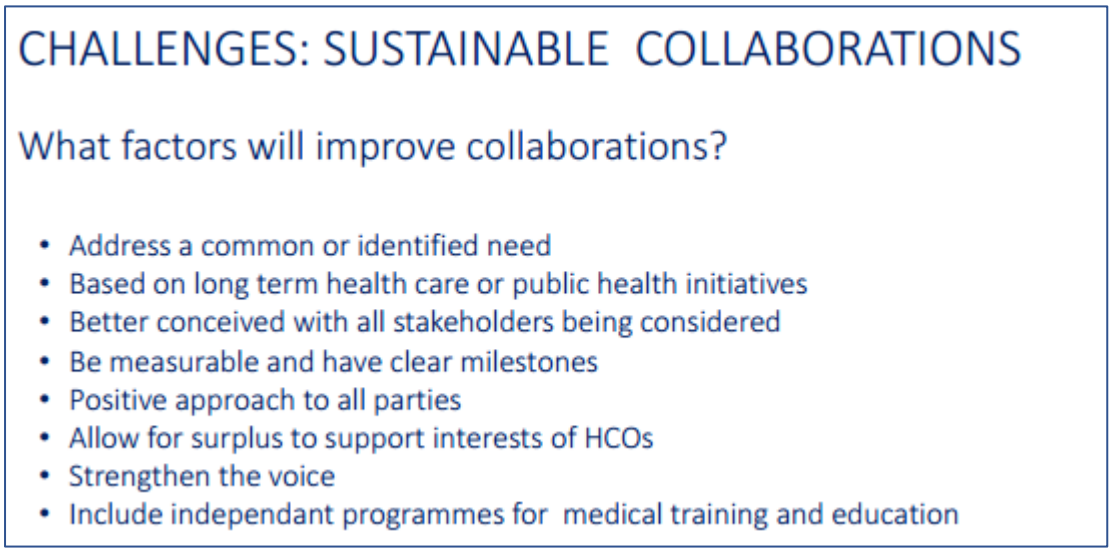
REGULATIONS CAN RESTRICT COLLABORATION!
COLLABORATIONS SAVE LIVES!

Some problem areas with codes include –

- Differing interpretation of the law: Defining “members of the public”. Amsterdam regulators said nurses were the public and, as a consequence, congress organisers had to rearrange the exhibition hall and use security to protect pharma stands. Although, this view has since been changed following discussion with local regulators, there are still clear issues in this area in other countries.
- Over regulating: What’s a gift? – At one meeting delegates were asked to sign a document acknowledging that a croissant was not a gift!

- Sensoring important materials: Symposia content regulations can prevent interesting data being shared with delegates.
- Disclosure and contract terminology. For example, you can't 'sponsor an advertisment'; rather you buy advertising space.

There are problems of COMMUNICATION AND CLARITY in interpreting the codes and guidance from the regulators. It is not always clear who to liaise with, who is providing the definitive legal advice and who is responsible for policing. Lack of consistency in interpretation is also a problem both between companies, between regulators and between nations. A new initiative might seem compliant to one company but not to another. Sometimes regulations can seem inflexible and petty and appear to be intended to prevent and limit collaboration. Steve Sealy commented that there were no meaningful interactions with some authorities e.g. France.



Visual from Steve Sealy, ERS

In summary, all stakeholders need to focus on the priorities and challenges in medicine and work together to set a working practice that allows for collaboration within reasonable, consistent and clear guidelines. If Industry, regulators and medical societies work independently then the likelihood of realising the potential of collaborations between industry and medical societies will not be met.

There was a discussion about the feasibility of a central funding body to which companies could contribute, but it was pointed out that this would simply create a tendering process and probably would not improve the situation.

A comment was made that funding might be directed at the wrong people to attend congresses. Senior people who could afford to pay their way but they got most of the funding. The need for transparency was also emphasized.

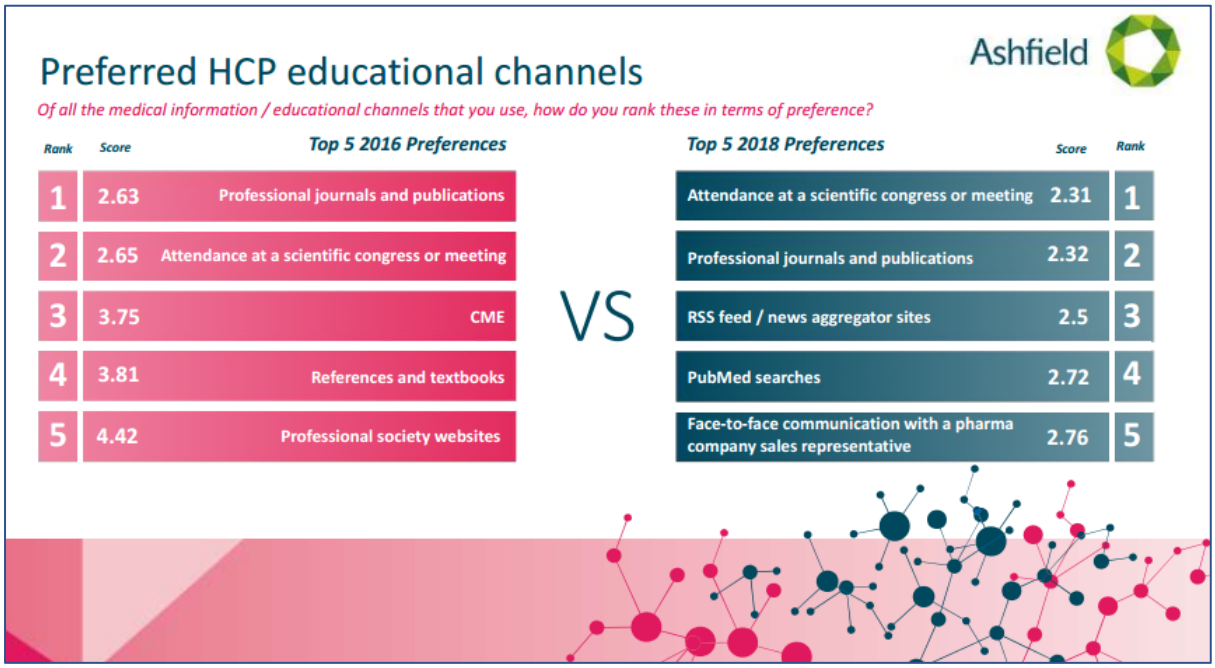
The science of HCP meetings

Lee-Anne Penn and Andrew Moore presented some of the key findings from Ashfield Meetings and Events 2018 follow up to their 2016 'Future of Meetings' white paper comparing and contrasting perceptions of HCPs. This latest survey was able to dive deeper into the ongoing evolution of the medical meetings landscape.

Full details can be obtained from the Ashfield website.

The areas covered were US, UK, France and Germany and specialities covered were cardiology, oncology, neurology and diabetes/endocrinology. The basis was 237 respondents who had attended at least one scientific meeting (with an average of 5) within the last 12 months.

Attendance at a scientific congress or meeting had now just overtaken Professional journals and publications as the preferred channel for education. These two options were also the most used channels.



Visual from Ashfield

Content and networking remain the major motivations for attending meetings. Note that HCPs do NOT go to meetings to visit a new city! An important motivator is that at meetings they are able to ringfence time from their busy daily lives to learn.

There was continued concern that industry codes of practice are increasingly restricting physicians' ability to attend meetings – but the level of concern had not increased in the past couple of years.

Only 30% of HCPs had given consent for Transfers of Value to be made transparent and interestingly 32% didn't know what Transfer of Value meant. 75% believe the industry has not provided a sound explanation of the meaning of transfer of value.

Managing workload when away from the practice and cost of attendance were two major barriers to meeting attendance and both were more challenging than in the previous survey.

There was also an increase in the value seen in patient centricity being a feature of the event.

Patient Centricity vs Code Complexity

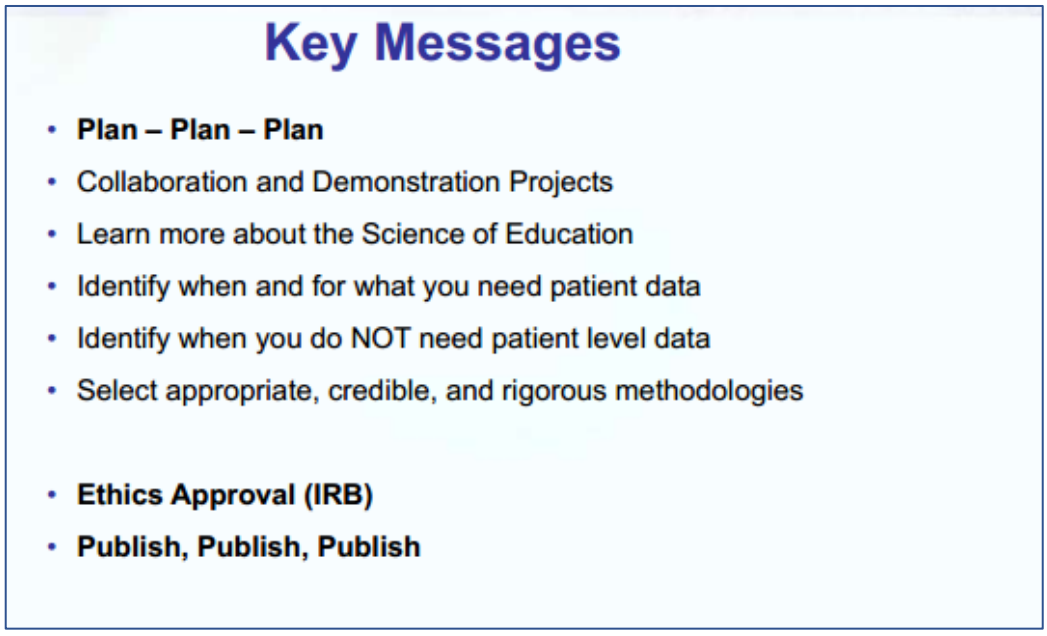
Reflecting one of the major findings from the Ashfield study the seminar turned its attention to patient centricity with two presentations. The first from a medical education specialist and the second from a patient representative

Patient Centric versus Code Centric

Suzanne Murray of AXDEV group said that HCPs want clinical decision-based solutions. Normally societies measure satisfaction but it's better to measure impact on patient treatment i.e. the care actually given. Patient cases are a more impactful way of learning than lectures.

It's good to have patient-level data in needs assessment for education. Patients are the ultimate benefactors of health education and performance improvement in health care. They are a source of data regarding health care providers' competence and performance and a patient-centric model provides patients' insights and experience. These are the critical parts of health care systems.

Suzanne set out her key messages with Plan, Plan, Plan being the number one.



Visual from Suzanne Murray, AXDEV Group

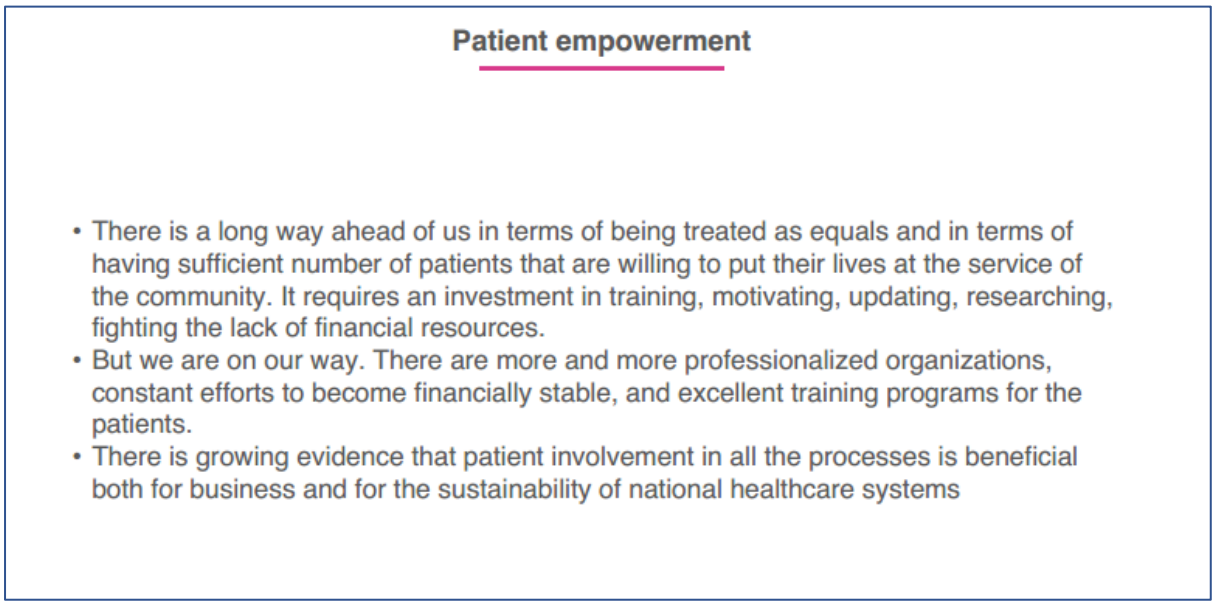
The patient perspective

Juan Fuertes, Managing Director, PHA (Pulmonary Hypertension Association) Europe asked, 'What is the law for?' and gave the answer 'To uphold the fundamentals of society.'

In continental Europe patient advocacy is quite new, generally less than 30 years, and has been mainly service orientated. Financial constraints make it difficult to 'professionalise' patients, so it can be difficult to engage them. However, in last 15 years there has been great progress. National organizations have an ever-growing knowledge and experience of the daily struggle and the unmet needs of patients. Patient organizations are more and more aware of the need of training and the need to cooperate in gathering information and collecting and providing evidence.

Patients and patients' representatives are now heavily involved in Health Technology Assessments, the EMA processes of approval and with European legislative bodies.

Codes can have the effect of excluding patients. Patients should be kept away from promotion, but most patients understand the difference between promotion and non-promotional information.



Visual from Juan Fuertes, PHA

Compliance must be there to prevent the possibility that patients' representatives or patients' organizations might be subjects of bribery, corruption, or manipulation. It should not be there to protect the patients from the supposed threat of not having the capacity to distinguish between advertising and real treatment benefits.

Panel Discussion

Christian-Claus Roth chaired the final lively panel discussion with Andrew Moore, Suzanne Murray, Juan Fuertes, Jan Wesiack (IPCAA), Sue Egan (ETHICS) and Steve Sealy. Here are some of the points made:

There too many levels and complexity impacting participation and implementation of industry in congresses. EU directives + national laws+ EU industry codes (efpia:medtech etc) + national code s + internal industry interpretation and none of these are known or apply directly to HCPs !!

Collaboration is key and the more the better !

There is a lack of consistency within many companies between those who deal with congresses, R&D staff, top management, compliance and legal dept and suppliers/ agencies who deliver booths or services.

We must have a consistent and strong communication on the value and outcomes for society & the patients of the collaboration

Medical societies have an image deficiency as they are little or not known by the public and even by some policy makers (not to mention some of the compliance officers !)

One idea is to invite medical societies to meet with the companies and exchange with as many parties as possible , this has been done and has been very positive

Attendance at virtual meetings has declined – a surprise

People don't stop and watch a congress on line. – they don't have the time to dedicate to this. We need to work out which bits do work online

Sometimes codes are blamed unfairly

Regulations come from lots of different directions – Association codes, company rules, CME etc. so lots of reasons to say no!

Confusion over application of rules well illustrated by a meeting where streaming to hubs in major cities was made possible. Companies could sponsor hubs and could add their own events. Some companies said this was compliant but some said they weren't allowed to be sponsors

Sometimes different interpretations from different people in the same company

Maybe Biomed Alliance could be more proactive in facilitating common understanding?

When codes were developed this was done without medical society input. In future medical societies would be pleased to cooperate.

"Patient Access Partnership "– a patient led group aiming to work with the EU parliament

Patients should not be excluded from medical conferences. Law may require that they are excluded from the advertising in commercial exhibition – but not from the scientific exchange.

EFPIA have put together a white paper which will be launched soon – it involved lots of consultation – it concerns working with patients

We don't want DTCA

Patients should be included in scientific sessions in same room – not separate sessions for patients – it's patronising

An educated patient is important. Uneducated patients arepotentially dangerous.

Don't treat patients like children!

Patients can bring a lot to a scientific forum – but mainly called just to put a face to a disease. Human face of disease is important but not the only possible contribution

There's a big need for interaction but most training is didactic. Discussion of real life issues is important

Rare diseases may be a special case for greater patient involvement – already often patients and doctorss in same room

Healthcare industry has made huge steps but corruption remains a problem across the world and across different sectors.

The rules have to be extended to the small individual professor led luxury meetings. They are still going on. Companies should not support these.

Compliance problems in healthcare are more with older doctors – younger doctors tend to be totally compliant. Teaching old dogs new tricks is a difficult task