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in-depth report from a meeting held in London, UK, 4–5 November 2008

by Eugene Pozniak

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European CME Forum: First Annual Meeting

in-depth report from a meeting held in London, UK, 4–5 November 2008

by Eugene Pozniak

Executive summary

The European landscape for continuing medical education (CME) is diverse and complex. The absence of a common framework across the region has led to individual countries developing their own national objectives and building a range of systems, each at differing stages of advancement. While similarities in approach exist, the key European markets demonstrate notable differences in both style and in how CME is being implemented. Nevertheless, a widespread appetite for collaboration and sharing best practice is driving European CME forward.

Despite such a fragmented and disparate environment, efforts to develop a recognised system for CME accreditation across Europe and to establish a harmonisation of credits and practices are progressing. Definitions of CME remain subjective and discussions continue as to whether it should just address levels of knowledge and competence, or go further and have a positive effect on clinical performance. Determining which activities actually constitute CME is similarly challenging: activities such as e-learning promise to provide the engine for CME in the future, whereas the accreditation of satellite symposia remains contentious. Meanwhile, traditional activities such as conferences and workshops continue to dominate.

In such an evolving climate, two central issues for CME development in Europe resonate loudly: the quality of programmes and the impact they have on clinical practice. Stakeholders remain determined to ensure that education is not only free from commercial bias but that it also promotes participation that leads to better clinical outcomes.

This Conference Insights report provides an in-depth review of the first annual meeting of the European CME Forum held in London, UK on 4–5 November 2008. It examines the development of CME activity across Europe, providing perspectives from the full range of stakeholders: healthcare professionals, medical societies, pharmaceutical companies, medical communications agencies and CME accreditation bodies. It explores the need to set quality standards in European CME, and to achieve harmonisation across the region. It shares implementation strategies and assesses how best to measure their success. It also looks at the critical aspect of funding, providing a basis for guidelines on how to manage conflicts of interest, avoid commercial bias and, crucially, raise standards. Clearly, maintaining a balanced relationship between healthcare professionals, CME organisations and the pharmaceutical industry remains pivotal to the future of CME.

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Introduction

The aim of the first meeting of the European CME Forum was to bring together all the stakeholders of European continuing medical education (CME), examine the current picture of CME (specifically in Europe), promote dialogue between the various parties involved and review the issues affecting its development. This included representation from the CME accreditation bodies, European medical societies and other healthcare professionals, members from the pharmaceutical industry and the service sector: the agencies included a few organisations that describe themselves as CME providers, as well as publishers, medical communications and public relations agencies.

The audience was overwhelmingly European, with a few delegates travelling from the USA and Canada, and one from Singapore.

The meeting took place over 2 days and was structured so that it addressed the widest scope of topics that touch on European CME. Each day followed the overall structure of theory – practice – application, with presentations covering the accreditation process (including regulatory and approval issues), how CME is viewed and used by the healthcare professionals themselves and, lastly, a review of several examples of educational activities that had been accredited for CME in Europe.

About the author

Eugene Pozniak is Programme Director of the European CME Forum and also Managing Director of Siyemi Learning, an independent European CME provider. He has worked in the medical sector for 20 years. Following a degree in chemistry, he initially worked across various functions in marketing and medical communications. Since 2000, he has been working exclusively in CME.

As well as managing CME-accredited meetings, Eugene developed the first pan-European CME-accredited e-learning (launched in 2002), national CME-accredited portals and has been working on European journal CME. In addition, he has developed a number of bespoke CME and 'non-CME-non-promotional' projects. Eugene has experience of CME across Europe, the USA, Asia Pacific and Latin America.

In 2006, Eugene founded Siyemi Learning, an independent provider of CME programmes and related services; he also supports the European CME-CPD Academy, an independent platform for accredited e-learning in Europe.

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Developing the meeting programme

The meeting opened with the Programme Director, Eugene Pozniak, giving an overview of the feedback received from potential delegates in the run-up to the meeting itself. These data were collated through an online survey for visitors to the meeting website and through e-mail exchanges. The answers helped to identify the educational needs of the delegates and to shape the programme. When asked what they thought were the most important issues facing European CME today, the following answers were given (in order of popularity):

- maintaining quality standards
- relevance to clinical practice
- harmonisation of credits across borders
- e-learning/additional channels
- industry funding
- managing conflicts of interest
- mandatory CME
- national government support.

When asked what they wanted to learn more about, the most popular answers were:

- CME status across Europe 82%
- measuring educational outcomes 71%
- e-learning – status and uses 69%
- how to identify educational needs 69%
- bias and conflicts of interest 53%
- how to plan and implement a CME activity 49%

A series of questions designed to evaluate opinion on how involved the pharmaceutical industry should be in CME presented a picture that showed overall support, with some clear messages from each group, but with only a single person – from a drug company – declaring that pharma should have no involvement in CME at all (Fig. 1).

National CME

The opening session of the meeting covered national overviews from the key European countries and the USA. The speakers highlighted how no country is simply copying an existing framework of a more

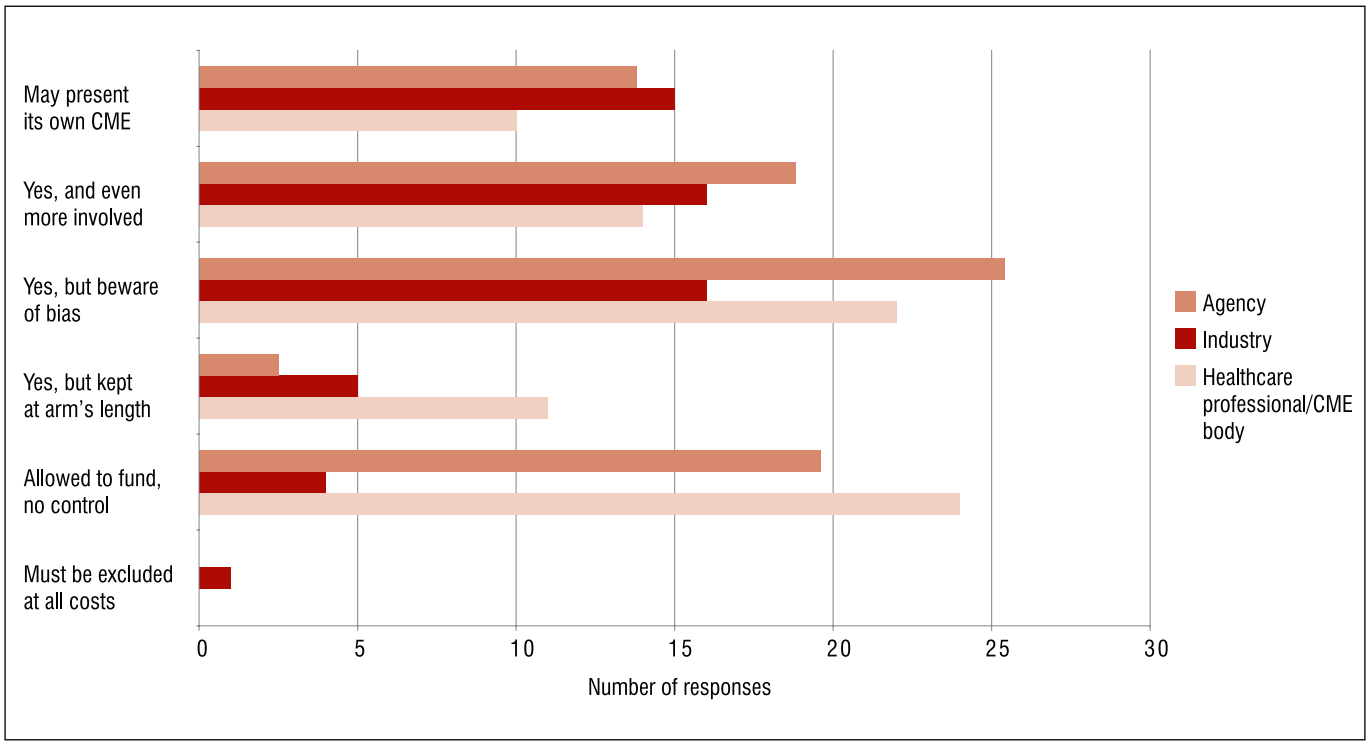

Fig. 1. How far should pharma be involved in European CME?

experienced country, and that each system is undergoing development with clear national objectives in mind. This in turn gives rise to a variety of styles of CME systems across Europe and the speakers illustrated both where there are similarities in approaches to CME, as well as the notable differences in how CME is being implemented in their own countries.

Germany

Dr Jörg Ansorg (Professional Board of Surgeons, Germany) – whose presentation was jointly developed with Dr Johann Weidringer (Bavarian Medical Chamber) – detailed developments in Germany and its recently revised CME system. Whereas CME has become mandatory for German physicians, there is inconsistency between the 16 states and the central Federal Medical Association (which does not have a CME competency itself) in what can be accredited and the procedures each follows. There are about 500 professional CME providers (scientific or professional boards and associations) and "countless" commercial providers. The regional chambers are responsible for managing the systems and CME certification, and the Federal Medical Association is working on the harmonisation and mutual recognition of CME credits within Germany. Ansorg highlighted that in essence there are 17 separate organisations in Germany each with its own system, with a complex bureaucracy to match involving a highly computerised authentication system with cards and bar codes; in effect a 'CME passport'. But with such a highly controlled process, the main concern is the efficiency of CME as a means to demonstrate a physician's competence, as it acts as little more than an attendance record. He highlighted the proposal of Weidringer and the Bavarian Chamber of Physicians for a broader model of CME, which encompasses continuing professional development (CPD) and takes medical education from merely expanding academic knowledge and skills to looking at how doctors apply the skills and knowledge gained to actually improving clinical practice. This could be achieved through the use of more thorough educational needs analysis, self-reflection, peer-review and 360-degree analysis to identify the best personalised CME programmes that should be followed.

There is a proposal in Germany for a broader model of CME, which encompasses CPD

Italy

The position in Italy was described by Dr Alfonso Negri (Italian Federation of Medical Societies), who discussed how the CME system there is evolving – moving away from a tightly controlled centralised system, with a greater emphasis on clear educational objectives during the review process. Currently, the system is similar to that in the rest of Europe, where the educational programme is accredited; however, Negri indicated that the system is going to move to one where providers will be accredited – this may come into effect as early as 2009. The structure for control will move away from the Health Ministry, take on a strong regional role and be controlled through the Agency for National/Regional Health Services. Accredited providers will be drawn from educational and professional bodies such as hospitals, universities and medical societies; commercial providers will not be allowed. The provider will review and accredit materials according to rules and regulations as determined by the Ministry of Health CME Commission and will be inspected periodically.

The new system will integrate the various regional structures and aims to improve the quality of education and its relevance to clinical practice. There will be clear rules of separation of pharmaceutical company support from the education provided and more emphasis will be placed on the disclosure of interests of all parties involved. Physicians currently do not pay for their CME in Italy, and it is expected that this will continue. The new structure will also look to recognise international CME, with an initial suggestion that CME credits gained outside Italy should be accepted at 50% of their face value. Once these changes have been put in place, Negri suggested that Italy will start to look at implementing a re-certification structure. In the meantime, while CME is still voluntary, and with these changes about to be put in place, the regional structure will continue with multiple providers. He noted that Lombardia is one of the most active regions, working with bodies such as the European Accreditation Council for CME (EACCME) and the Baden-Württemberg Chamber of Physicians in Germany on the reciprocity of credits, and is currently the only region in Italy to accredit e-learning programmes.

France

Dr Bernard Ortolan (National Council for Independent Physician CME, France) described the history of CME in France and its long path from legal requirement to actual reality. CME was made mandatory in 1996 but this requirement was not actually enforced until the Council for CME (CNFMC) was set up in 2004 with its three constituent bodies:

- Council for CME of Independent Physicians (CNFMCL)
- Salaried Non-hospital Physicians (CNFMCS)
- Physicians, Biologists, Odontologists and Pharmacists working in Public health (CNFMCH).

Ortolan pointed out a drawback with traditional CME in that it tends to address perceived needs rather than specifically addressing a measured need. The French have started addressing this by using a Deming Wheel (The Plan-Do-Check-Act Wheel) approach, an important part of which is the Professional Practices Assessment

(EPP), a process that looks at a physician's clinical practice. Even though the current CME system is under review and changes are expected to be announced shortly by the Minister of Health, the current system is still running. The French have a system of accrediting providers – education providers apply to the relevant council and are then reviewed for their suitability for accreditation. Of the 650 applications to date about 445 have been evaluated with 285 being granted accredited status. There have recently been applications from e-learning agencies to be able to accredit online learning, the first of which was due to be evaluated the day after this meeting.

Traditional CME tends to address perceived needs rather than specifically addressing a measured need

Ortolan detailed how CME is funded differently in France, where health professionals are willing to pay for education. Pharmaceutical companies account for less than a quarter of CME, with social welfare systems paying for about half; physicians pay for the remainder either through membership fees or at the point of learning. Ortolan expressed his desire to see the French credit system harmonised within a European-wide system. He also noted the imminent formation of a French College of General Practitioners, expected before the end of 2008, which he hoped would support the work of the European Union of General Practitioners to develop a similar structure to the one established by the European Union of Medical Specialists (UEMS). As far as the future of CME in France is concerned, the medical community now awaits the judgement of the Minister of Health in early 2009.

Spain

Juan de la Fuente (Wolters Kluwer Health, Spain) presented slides on behalf of Dr Hèlios Pardell (Spanish Accreditation Council for CME [SACCME]). Fuente discussed how commercially supported CME is the main route for developing CME programmes in Spain, running at an estimated 80% of all programmes. While CME is not mandatory in Spain it is actively participated in by doctors. Fuente described the external peer-review process used to assess an educational activity for CME accreditation. The 'learning profile' is judged by a number of standards, including a 'quality factor' determined by the style of output. Those activities using more engaging learning techniques attract a higher factor when working out the final credit value to be awarded (rather than a straight 1 hour = 1 credit model). This system has led to a discrepancy with other European systems, but in order to allow for cross-border recognition, it was agreed recently with the EACCME that 1 ECMEC (European CME Credit) is equivalent to 0.12 SACCME credits. Medical societies and associations present about half of all CME in Spain, with pharmaceutical companies accounting for about 15% of all programmes; however, Fuente noted that 65% of funding for all CME activities ultimately comes from pharmaceutical companies and about 5% of activities are directly funded by the physicians themselves.

CME is not mandatory in Spain, but is actively participated in by doctors

The Netherlands

Dr Peter Polak (European Board of Accreditation in Cardiology [EBAC]) noted that The Netherlands has a mandatory CME system. The 5-year accreditation cycle looks at quality through three 'pillars':

- 'Guidelines' (and how to treat specific conditions)
- 'Accreditation' and the number of CME credits the physician collates annually
- 'Visitation', where each specialist receives a peer visit by two related specialists every 5 years, to look at how the physician actually carries out their work.

The Netherlands has a mandatory CME system

Polak noted that it is rarely a lack of knowledge itself that leads to problems, but usually problems in communication, attitude or organisational structure. The Dutch Government also has an influence in terms of the certification and re-certification of doctors, also conducted on a 5-yearly cycle, in which physicians need to demonstrate that they have been actively working for over 16 hours per week, have gained enough CME credits (40 per year) and have also successfully participated in Visitation. Failure in any of these requirements leads to unsuccessful re-certification.

UK

There were two presentations outlining the situation in the UK; following the recent publications by the government on the regulation of health professionals[1] and the White Paper on the re-validation of doctors (Fig. 2),[2] the Royal Colleges are working towards addressing these requirements and progressing CPD for their respective specialists. Professor Nigel Sparrow (Royal College of General Practitioners [RCGP]) described the system for GPs, and Dr Alistair Thomson (Academy of Medical

Re-validation = Re-licensing + Re-certification
where re-licensing demonstrates that the doctor practises in accordance with the GMC's generic standards and re-certification confirms that he/she continues to meet the standards that apply to his/her discipline, as managed by the Royal Colleges

Fig. 2. Re-validation in the UK.

Royal Colleges) gave the perspective of doctors working in secondary care.

Sparrow described an existing flexible framework for GPs but one based on a clear structure. He referred to the RCGP's *Good Medical Practice for General Practitioners*[3] as the cornerstone of all activity and, as developments progress towards re-validation (expected around 2010), the RCGP is putting into place some principles and activities to help facilitate the new process. Although there are two parts to re-validation, with re-licensing being looked after by the General Medical Council (GMC) and re-certification the responsibility of the Medical Royal College, the RCGP sees the two parts as a seamless process.

Sparrow reviewed the principles of good medical practice, which comprise: knowledge, skills and performance; safety and quality; communication, partnership and teamwork, and maintaining trust. CPD falls under knowledge, skills and performance, and is a system of learning that is based more on the impact of learning than the time spent on it. Every GP has an annual appraisal in clinical governance, which examines several items relating to clinical and non-clinical aspects of their practice, including CPD. The GP reviews his or her educational needs, whether they are identified or met, and agrees a personal development plan for education over the next 12 months. GPs accredit themselves as they undergo educational activities to meet this plan, which can also include e-learning and a flexible section under the title of Hot Topics, aiming for 50 credits per year, and review with their appraiser the following year whether or not they have met their requirements. Currently, this is an annual activity, moving to a system of five appraisals over the 5-year re-validation cycle. Sparrow also described how the view of CPD, in terms of an impact and challenge model, can be used to allow for variance in the amount of credit an activity would be worth: thus a low-impact activity that does not challenge the doctor would warrant a lower credit level than an educational activity that was demanding and had an impact on clinical practice and patient care.

Thomson gave details about the system in secondary care and the broadly similar plans to introduce a system of re-validation, encompassing re-licensing and re-certification, with the intention of looking at positive

Summary of current European national requirements

Country	CME requirement	Incentive	Sanction
France	• 'Mandatory' but still voluntary in practice • Recommended 250 credits over a 5-year period	Currently none	• Effectively none
Germany	• Mandatory • 250 credits per 5-year cycle (50 per year)	Currently none	• 1 year: 10% reduction in fees • 2 years: 25% reduction in fees • After 2 years: potential for withdrawal of licence (hospital-based physicians are governed by their employer)
Italy	• By law since 1999 • 50 credits per year (3-year cycle), but still not clear	None formally, but can be used to further professional career	• Currently none
The Netherlands	• Mandatory requirement for re-certification • 40 credits per year (5-year cycle)	Currently none	• Threat of non-re-certification
Spain	• Voluntary • No recommendations	None formally, but can be used to further professional career	• Currently none
UK	• Recommended 250 credits per 5-year cycle (50 per year)	Currently none	• Currently various sanctions through Royal Colleges • Expected soon: threat of failed re-licensure or re-certification

affirmation and not just confirming an absence of concerns.[4] The system for hospital doctors will also run over a 5-year cycle, with CPD playing an important part. Re-licensing will follow a set of standards set by the GMC and a CPD framework based on a formative and summative appraisal process. CPD will encompass good clinical care, maintaining good medical practice, teaching and training, relationships with patients and working with colleagues.

The UK is introducing a system of re-validation for health professionals, encompassing re-licensing and re-certification

Whereas CPD in the UK is based on a model of self-approval, it is possible for education providers to apply for a commercially supported event to be reviewed for CPD approval. (Dr Ian Starke of the Royal College of Physicians [RCP] presented details outlining some of the specific requirements for approval by his College later in the meeting; see page 16.) Thomson stated that events approved by one Royal College are recognised by reciprocal agreement by other Medical Royal Colleges or their Faculties, and the Royal Society of Medicine, with the exception of the RCGP which, as was mentioned earlier, runs a slightly different system. Thomson noted that in a recent review of CPD activity in his College (the Royal College of Paediatrics and Child Health [RCPCH]) there has been a decline in CPD engagement by its members over the latest 3-year period (2002–2004 being the most recent dataset that was analysable), in which 48% of a sample audited (n=118, ~5% of eligible members) provided scant or non-existent evidence of having taken part in CPD. The reasons were unclear but the expectation is that this would change once re-validation is implemented.

USA

Lawrence Sherman (The Physicians Academy for Clinical and Management Excellence, USA) described how the status of CME in the USA is continuously in a state of evolution. While identifying that, as in many situations, it is the actions of a small group of people that tarnish the image of the majority, CME needs to move forward and focus firmly on the main objective: improved patient care. This is not necessarily down to how an educational activity is funded, and just because an activity is CME accredited does not necessarily make it good in itself. Sherman described "good CME" and "bad CME", discussing examples of each, and identifying the main issue to the learner, that of the relevance of the education.

When Sherman examined whether US CME is in crisis, he saw it as being in a state of flux, one that can promote change for the better. A positive factor that he identified is the increasing popularity of 'performance improvement CME',[5] a system that offers the learner more relevant education, helping, for example, to focus on the patient, and not just on an individual condition.

CME needs to move forward and focus firmly on the main objective: improved patient care

European Specialty Accreditation Boards

While the roles of national accreditation authorities are comparatively clear in their function as national arbitrators, another route for CME-accredited programmes is through the European Specialty Accreditation Boards (ESABs). These have come into being through a number of different routes and they have varying levels of influence. Most have come about through the initiation and further control of the European specialty medical societies, many of which have a relationship with the UEMS and its CME accreditation arm the EACCME (about which further details appear on page 13).

Dr Peter Polak described how, in 2001, EBAC arose as a joint initiative of the Cardiology Section of the UEMS and the European Society of Cardiology. As well as accrediting live events it is also prepared to accept other educational media, such as e-learning, CME articles, textbook chapter reprints and even virtual reality CME. Over the years, it has secured official recognition from 27 national cardiac societies and two National Accreditation Authorities (NAAs), allowing for widespread recognition of its credits. Crucially, in November 2007, EBAC formalised a cooperation agreement with UEMS-EACCME, bringing the two organisations much closer together and establishing an integrated working relationship. This agreement means that all applications for any programmes in cardiology that are submitted to UEMS-EACCME are automatically directed to EBAC for evaluation; the accreditation granted is recognised through the European NAAs and falls under the agreement that the EACCME has with the American Medical Association (AMA) that 1 ECMEC is equivalent to 1 AMA PRA Category 1 Credit (the CME credit system in the USA). The new accreditation procedure will be reflected in the updated online application procedure available from the EBAC website. EBAC most notably no longer accredits commercially supported satellite symposia, and has explicit rules for what they will accredit, most notably that the provider needs to be an "(inter)national professional medical society", university or teaching hospital.

EBAC accredits live events and other educational media, such as e-learning, CME articles, textbook chapter reprints and even virtual reality CME

Professor Robin Stevenson (European Board for Accreditation in Pneumology [EBAP]) gave an overview of European CME as it has developed in recent years. He highlighted that in these, still early, days there is a grave risk of CME bodies acting as "policemen with rubber stamps", enforcing draconian rules while losing sight of what is of highest quality or indeed need. He discussed recent studies that looked at the effects on outcome and changes in practice and the disappointing results they reflected – that most CME is didactic rather than interactive and not making demands on the learner. In 2006, to examine this further, the European Respiratory Society invited representatives from 13 specialties to meet to discuss all aspects of current practice and agreed to carry out a survey of current practice. They found that:

- quality criteria were observed by less than 40% of UEMS sections
- over 60% of respondents were not satisfied with the manual processing of applications
- almost 80% of respondents were in favour of a common internet platform
- Between 60% and 70% of respondents thought that distance learning would be important in the future.

Stevenson described the expectations EBAP has when reviewing a programme for accreditation – they would like to see evidence of the systematic assessment of educational needs and careful programme development. The programme should also reassure learners that the education is free from commercial bias and promotes participation such that it improves clinical practice leading to better clinical outcomes.

ECCO has also developed a framework to endorse the quality, value and recognition of CME and works closely with ACOE to evaluate the quality of CME events in oncology

EBAP also uses an electronic submission platform and is used as the specialist reviewer as part of the EACCME review process, which also involves the relevant NAA. Applications for accreditation of e-learning programmes can be made directly to the EBAP and, as it develops closer cooperation with EACCME, a more centralised application system will be put in place.

In the case of oncology, Michel Ballieu (European CanCer Organisation [ECCO]) outlined the work of ECCO, which also gave rise to the Accreditation Council of Oncology in Europe (ACOE). He spoke about the challenges that ECCO – a federation of 24 European Cancer Societies – faces when serving a diverse group of healthcare professionals in a specialty area with numerous subspecialty groups, which includes 200 diseases and three main disciplines (i.e. oncology surgery, medical oncology and radiation oncology). Added to this, the lack of streamlined recognition across Europe means that the professions are poorly recognised as discrete groups and the heterogeneity of training practices raises many problems.

Ballieu described the challenge undertaken by ECCO to develop a framework to endorse the quality, value and recognition of CME, which resulted in the creation of the ACOE, an independent ECCO Committee with the function to assess the quality and educational value of CME activities. Finally, Ballieu explained how, in addition to the established work with international conferences and EU advocacy, ECCO is now developing e-learning for oncologists and researchers and also develops web-based information for patient advocates.

Professor Dieter Hossfeld (ACOE) explained that oncology, by its nature, must be multidisciplinary, being a disease that does not respect organ limits, thus involving many specialists. As well as highlighting the need for an organisation with the structure of ECCO, Hossfeld described the background to creating a CME accreditation organisation to match. In this context, he raised the issues of the free movement of oncologists across borders, the problem that there are no standards for postgraduate education and the need to demonstrate the maintenance of skills. He outlined how ACOE has representation from the leading European oncology societies working in partnership with the UEMS-EACCME. Professor Hossfeld highlighted, in particular, the latest ACOE developments in relation to the accreditation of e-learning CME material.

CME bodies accrediting e-learning in Europe

NAAs	***ESABs***
Germany	EBAC
Spain	EBAP
UK	ACOE
France (theoretically)	EACCME (from early 2009)
Some regions in Italy	

A body that has no relationship at all with UEMS-EACCME, and which was born in unique circumstances, was outlined by Dr Daniel Souery (European Accreditation Committee in CNS [EACIC]). EACIC came about as an initial idea for a European Community-funded "Leonardo da Vinci Programme" project called "Developing Cross National CME for Mental Disorders in Europe". The funding allowed for a project group, in collaboration with the European College of Neuropsychopharmacology (ECNP), to assess the different CME systems across Europe available for physicians working in CNS and to start setting objectives for a common European system of quality control for CME in CNS. EACIC was the endproduct of this programme and it continues to develop evaluation and monitoring tools for CME activities.

EACIC has been accrediting the ECNP annual congress since 2002 and also reviews other international events in CNS which, Souery noted, tend to be in the fields of psychiatry and psychopharmacology. The evaluation process is carried out online; learners are asked a thorough set of questions about the programme and are asked to give a satisfaction score for each educational element. The EACIC office analyses the results centrally, issues the CME certificates electronically and generates a feedback report that is made available to the education provider.

EACIC's centralised procedure provides access to a broad range of statistics about the quality of educational programmes and usage information

Souery believes that in order to contribute to improving scientific and educational standards these data need to be analysed and reviewed rather than being just a utility for simple certificate delivery. This centralised procedure enables EACIC to have access to a broad range of statistics about the quality of educational programmes and usage information, which created some interest among the audience. Souery presented some top-line data; he showed how the number of requests for CME certificates has risen steadily over the 7 years of accrediting the ECNP annual congress, but he noted a levelling off in the past 2 years – attributing this to a potential reduction in interest in CME. Souery noted that in the evaluation questionnaires returned there was a consistently low score for the question: "How did CME and accreditation influence your decision to attend this event?", which he said demonstrated that while there is an interest in CME, it is not a driving force for people to attend meetings. He concluded that it is still the content and the quality of the education that matter most. When summarising and looking to the future of CME in psychiatry, Souery noted the gaps between systems and mutual recognition, and identified the need for EACIC to develop agreements with other national and European CME bodies, and especially UEMS-EACCME, to put in place mutual recognition of CME credits.

European Accreditation Council for CME

Bernard Maillet (UEMS-EACCME) outlined the background of the organisation set up by the UEMS initially as a clearing house for European CME. However, its role has since expanded and it is increasingly seen as a first port of call for CME accreditation in Europe (Fig. 3). UEMS was primarily concerned with representing the medical profession (mostly physicians in secondary care), but in 1999 it decided to set up EACCME as an accreditation arm. It has now successfully developed a widely recognised system for CME across Europe and has agreements with NAAs and ESABs working towards agreeing the ECMEC as a standard. While negotiating its way around various countries and organisations in various stages of development in CME, it is working towards harmonising credits and practices. It sees CPD as "…the educative means of updating, developing and enhancing how doctors apply the knowledge, skills and attitudes required in their working lives"[6] and prefers that CME is not mandatory for doctors; as Maillet pointed out: a voluntary system based on motivation, incentives and effective control systems is more desirable as a "carrot is more effective than a stick". It has also agreed reciprocity of credits with the AMA, with the ECMEC being considered equivalent to the US AMA PRA Category 1 credit. EACCME has an online accreditation system and recently declared its decision to start accrediting e-learning in early 2009.

CPD – "…the educative means of updating, developing and enhancing how doctors apply the knowledge, skills and attitudes required in their working lives"

Edwin Borman (UEMS CME/CPD Group) presented further details emphasising that this will also prompt a raising of quality standards in European CME.[7] As well as the usual requirements, there must be mechanisms in place to demonstrate the fulfilment of learning objectives with a clearly defined target audience. The education must be evidence-based and the e-learning should employ techniques promoting 'active learning', with a mechanism for confirming to the learner that learning objectives have been achieved. These criteria will help confirm high-quality CPD for the learner, and aim towards improving quality standards of CPD and, ultimately, learning and clinical care. Borman also described how

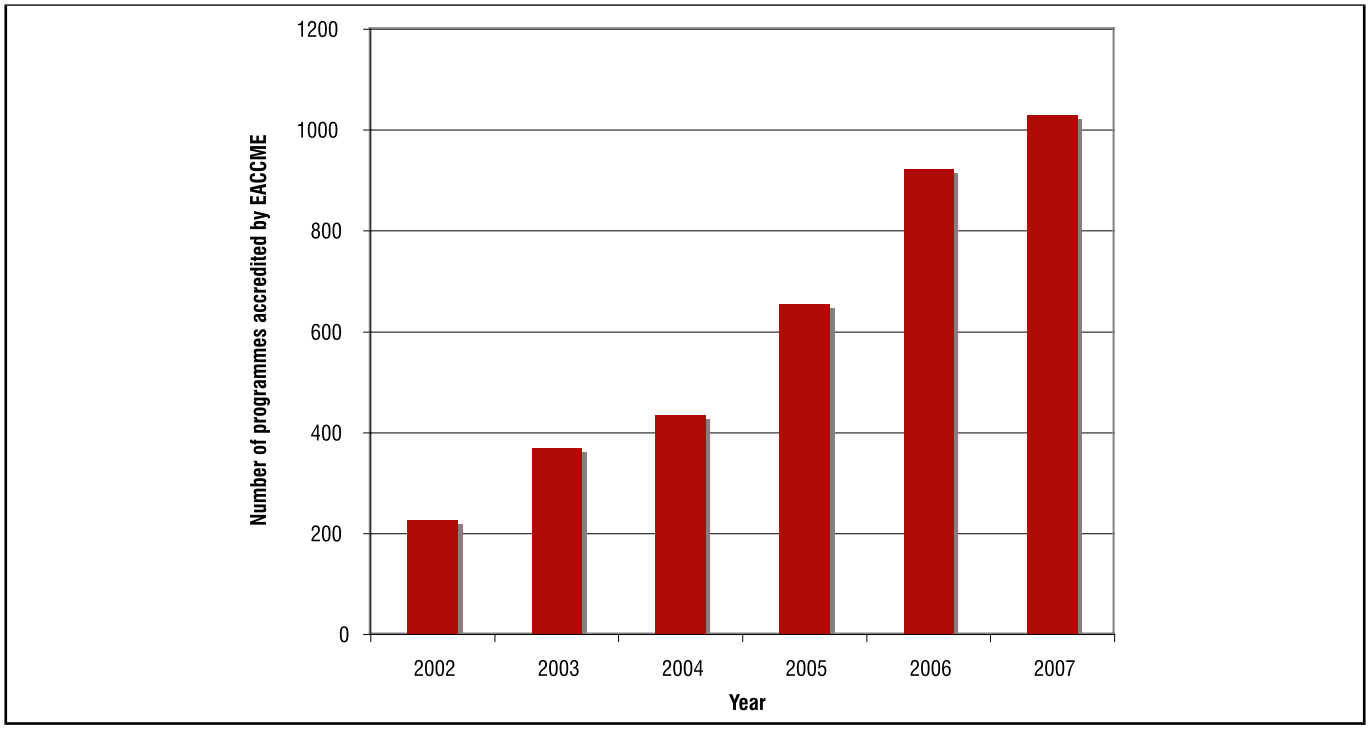

Fig. 3. The number of programmes accredited by EACCME has increased since 2002.

CME or CPD?

Continuing Medical Education
"improving what you know"
Competence

Continuing Professional Development
"enhancing how you practice"
Performance

Brief descriptions of CME and CPD. Reproduced with permission from Edwin Borman (UEMS CME/CPD Group).

these standards would be incorporated as a 'retrofit' into the accreditation by EACCME of live events.

CME in practice

In neurology

Professor Wolfgang Grisold presented some ideas on the kind of impact CME has on neurologists and neurooncology in Europe. He could do so from a multiple perspective, being active within a number of organisations including the European Association of Neurooncology (EANO, which is working closely with ECCO), the UEMS Board of Neurology, the European Federation of Neurological Societies and the World Federation of Neurology. He described the increasing shift away from CME to a more 360-degree view that CPD can offer the neurologist and oncologist. He raised the importance of a structure to the multidisciplinary approach that is needed, based on best clinical practice, to better serve the emerging markets of the newer EU member states in Eastern Europe. He presented a recent survey of the most popular instruments of education among neurologists showing that conferences are still a very popular way for neurologists to keep up to date (Fig. 4).

Grisold also discussed evaluating the outcomes of a CME/CPD activity. He cited a study that evaluated work carried out by the World Federation of Neurology in Eastern Europe and how, through a collaborative model in lifelong learning, good results were obtained without expending huge costs.[8] He also called for a sensible approach to interaction with the pharmaceutical industry with regard to CME funding, citing recent examples of clinical developments in treating migraine and multiple sclerosis as areas in which the pharmaceutical industry interacted positively, supporting education in these areas.

Setting quality standards in European CME

Dr Alfonso Negri presented some work of the Rome CME/CPD Group that was established in 2003; its members are drawn predominantly from CME accreditation bodies. The primary objective of this group is to bridge gaps between accreditation systems in Europe and around the world by bringing together the world leaders in CME/CPD and defining common guidelines in order to gain international reciprocity.[9] Negri explained how the aims of the group are to achieve globalisation and harmonisation by reviewing what works in CME and finding common ground.[10] The group also works in the area of developing common guidelines for commercial support and conflicts of interest. Its

approach has been endorsed by many organisations across Europe, some of which have adopted the guidelines explicitly. A "Common international CME/CPD glossary" and "Common guidelines for commercial support and conflict of interest" are due to be published shortly. The glossary will help to define many commonly used terms in CME so that there is a common vocabulary across Europe. The "Guidelines for commercial support and conflict of interest" will address:

- independence
- content and format
- disclosures relevant to potential conflicts of interest
- associated commercial activities
- guidance on statements regarding allocation of CME/CPD credits.

UK CPD supported by the pharmaceutical industry: the practical interface

The opening session of the second day of the meeting began with a specific look at the issue of managing conflicts of interest in the UK and the interaction between the pharmaceutical industry and the CPD approval bodies (the responsibility of the Royal Colleges). Dr Richard Tiner (Association of the British Pharmaceutical Industry [ABPI]) opened with some thoughts on a recent report from the Macy Foundation,[11] which concluded that lecture-based CME is largely ineffective, that the CME system is fragmented, poorly regulated and uncoordinated, and that commercial support is undesirable and should be withdrawn from CME. In a follow-up, the chair of the report, Professor Suzanne Fletcher, highlighted that any problems associated with conflicts of interest in CME are the learner's responsibility (i.e. they should subjectively assess any potential threat of bias), and that even though commercial support puts the teachers in the untenable position of being paid by the supporter, giving up commercial support will not be easy.[12]

Tiner highlighted the long tradition of support for CPD by the pharmaceutical industry and also the time in 2006 when, due to increased financial pressures, Primary Care Trusts and Hospital Trusts withdrew their budgets for education; had it not been for the welcomed support of the pharmaceutical industry there would have been little education taking place. There are no guarantees that the NHS will fund education. He highlighted the areas in which the new APBI Code of Practice,[13] now in its 50th year, addressed topics relating to the support of CPD, including the certification of meetings (clause 14.2), hospitality (clause 19.1) and declarations of sponsorship (clause 19.3). (A clause-by-clause summary of the major revisions to the ABPI Code of Practice, and how these may impact industry interactions with its stakeholders, can be found in another KeywordPharma review, *Tightening Regulations and Raising Standards in UK Marketing Communications: the New ABPI Code of Practice (2008) Explained*, by Steven Gray[14].) In developing these statements, the ABPI took guidance from the GMC publication, *Good Medical Practice*,[15] and discussed aspects with the Royal Colleges. Tiner clarified that the 2008 code is now based on that of the European Federation of Pharmaceutical Industries and

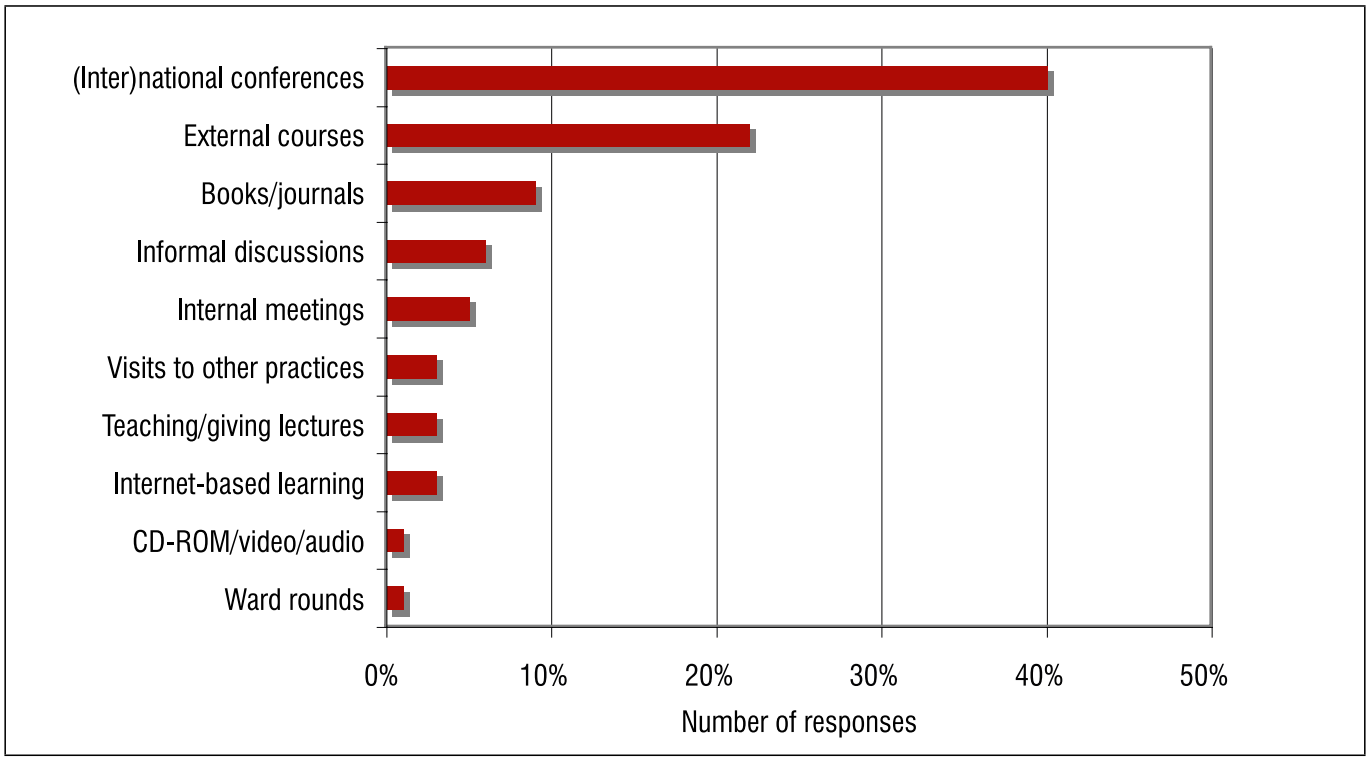

Fig. 4. A recent survey of the most popular instruments of education among neurologists. Data from Wolfgang Grisold (UEMS Board of Neurology).

Associations (EFPIA) and, once the new version of this is published in 2009, there will be greater homogeneity of regulations for the pharmaceutical industry across the EU. In addition, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) code is being increasingly opted for by countries further afield. Tiner concluded by questioning whether the medical profession would be willing to pay for their own CPD. In the UK, pharma-supported CPD rarely leads to justified criticism; without it, there would ultimately be an adverse effect on patient care.

In the UK, pharma-supported CPD rarely leads to justified criticism

Dr Alistair Thomson, presenting from the other side of the camp, outlined how it is the responsibility of each college to draw up guidelines on how to develop and present education, as well as the parameters for pharmaceutical company involvement. He noted that commercial sponsorship cannot touch all areas of education (e.g. reflective learning) and stated that organisations such as his (the RCPCH) are grateful for industry support to help meetings to take place, but that clear principles are followed: the RCPCH does not accept sponsorship from, or invest in, companies considered to be unethical, and when there are concerns the College discusses them, such as the recent debate about sponsorship from milk companies, when the College wanted to highlight some concerns about their promotional tactics in developing countries. Thomson outlined some of the guidelines that are given to presenters; most of these are drawn up in consultation with the other parties and the majority of points are consistent with the ABPI Code of Practice as well as the guidance from the Rome Group.

Dr Ian Starke continued with further information about the Rome Group, presenting some of the draft guidelines that are due for publication in early 2009. He also highlighted some positive points from the Macy Foundation report, especially the findings that didactic lectures are not necessarily the best way to learn and that workplace learning is very important. Starke proceeded to discuss points from the RCP guidelines and regulations for accreditation,[16] and gave an example of how the RCP had worked with the ABPI on parts of the new Code of Practice, as well as considering the Rome Group guidance, to ensure consistency between the different groups involved in a CPD activity. He identified a pattern emerging in the UK where there is consistency between the interests of the Royal Colleges through the Directors of CPD, the ABPI and the guidance from the Rome Group, with some work still to do on the detail.

The view from pharma

While the pharmaceutical industry has a long heritage of providing medical information and education, CME is an area that is relatively new to them in Europe. A company that has been delivering e-learning internationally since 2007 is MSD through the univadis® medical online portal. Dr Thomas Kellner (univadis, MSD) described how the intention is to create a 21st century equivalent of the Merck Manual. To be seen as an independent and trustworthy source of information, the decision-making process is demonstrably separate from the company's commercial interests and is funded from an isolated and independent budget. The reporting structure also avoids any contact with commercial interests within the company. The main aim is to build trust; univadis has been designed and built in collaboration with physicians and offers high-quality independent content driven by identified interests of the audience. Additionally, there are tight controls over promotion; the user is reassured by a clear separation of promotion from information – all educational areas are completely free from any promotion.

The e-learning is on a tailored platform that is appropriate for CME in countries where it is permitted for a drug company to offer it. Kellner presented some market research from users in Germany and France that explored quality indicators: there was a high demand for education of a high quality and a learning impact free from promotion, and for a flexible curriculum that could be tailored to the individual's own educational needs, and not a series of one-off engagements; additionally, users favoured education endorsed by scientific organisations. Experience has also elucidated that physicians do not see education just in terms of online courses alone: medical news, journal articles and slide kits are also important.

Physicians do not see education just in terms of online courses alone: medical news, journal articles and slide kits are also important

Dr Erin Kingshill (Eli Lilly & Company) presented another company with a tradition of providing non-promotional education to physicians going back over a century. Kingshill described the types of quality and transparency developments that Lilly has driven over the years since the late 1800s when it was the first to introduce labeling of its medicinal products and controlled its sales through the exclusive use of licensed pharmacists. She gave an overview of the driving factors behind the desire to improve individual patient outcomes through supporting education and enhancing the knowledge of the physician. Lilly has been supporting these kinds of initiatives for decades, and Kingshill stated that, with the appointment of a new President and CEO, and the setting up of the new division of global medical education, Lilly will continue in its work to deliver improved patient outcomes through the development

of learner-focused, reliable information and valued education.

Vincent Nys (Janssen-Cilag EMEA) posed the question of whether pharma should be more proactive in European CME by implementing a system of self-regulation, especially in an environment where there is no broad regulation, as opposed to the situation in the USA, where clear rules exist. He outlined Janssen-Cilag's own policies of supporting medical education, with all support for CME being clearly separated from the marketing or commercial functions of the drug company. This is something that Janssen-Cilag is implementing visibly. In addition, the company has established a requirement that any funds supplied should address unmet medical needs through high-quality, balanced information that is unbiased and of scientific and educational value, and which complies with all regulations regionally and nationally. Nys also touched on the topic of trust and drivers for companies in an environment that needs to be free from parameters such as return on investment; for pharmaceutical companies to succeed and gain benefit, Nys concluded that they must develop high-quality independent education that addresses unmet medical needs and improved quality of care.

Pharmaceutical companies must develop high-quality independent education that addresses unmet medical needs and improved quality of care

An interesting point was raised when the speakers were asked to comment on their willingness to support education in an area of medicine outside of their direct sphere of interest. All the speakers indicated that they felt qualified to contribute only in the areas in which they have the most experience and expertise, as they are obliged to; however, this same obligation specifically forbids them from providing services outside their areas of interest.

CME experience: the learners

Two presentations towards the end of the meeting covered quantitative data from physician studies. The first presentation, given by Professor Dr Peter Henning (Karlsruhe University of Applied Sciences, Germany), looked directly at the quality of education in CME. Henning presented information from a study in which a group of randomly selected physicians (general physicians and neurologists) undertook a CME-accredited course, either in a traditional print form or as an e-learning programme. Each group was tested for their level of knowledge before the activity and again on completion of the education, as well as being asked a series of subjective questions. The study findings showed that the average knowledge gain was significantly higher in the e-learning group, demonstrating the key superiority of e-learning over traditional print: the average individual knowledge gain for the print learners being 25% compared with an average of 50% for the e-learners (Fig. 5). Henning also looked at failure rates and noted a lower failure rate for the e-learners: none of them failed the test after the education, compared with a 20% failure rate for the print learners. Henning disclosed data that made the case for e-learning very persuasively: the majority of users answered in the subjective analysis that e-learning was more time saving, convenient, flexible and even fun. Henning finally observed that computers were now in widespread use among the medical profession and that computer-based education was no longer the domain of younger learners, with the average age of the participants in this study being 50 years.

e-Learning has been shown to be more time saving, convenient, flexible and even fun

Emma Sergeant (Ogilvy Healthworld, UK) looked directly at physician attitudes to the question of whether pharma should be involved in CME in Europe. Sergeant presented data from a biennial online survey of key clinical experts in Europe running since 2005. The sample of 400 European physicians was asked whether pharma should be involved in CME. Sergeant reported that 63% had already been involved in a CME project, with 44% actually helping with the production of educational materials. The key motivators for being involved in CME were, primarily, to improve patient care, to share knowledge among their peer group and to increase access to research data. When asked what they would like to see pharmaceutical companies do more of, the majority mentioned programmes to support patients (without product bias) and the provision and funding of more educational activities (Fig. 6), which, Sergeant noted, indicated a satisfaction with the current arrangement and confidence for further support from pharma. She concluded with data showing the interest shown by doctors in e-learning and how e-learning can help facilitate individualised learning and offer learners flexibility.

CME case studies

Two of the sessions at the meeting were dedicated to discussing actual case studies of educational programmes that had been accredited for CME by a European CME body. The first day concluded with an interactive session led by Lawrence Sherman and Cliff Wyatt (HealthCare21). The delegates were given

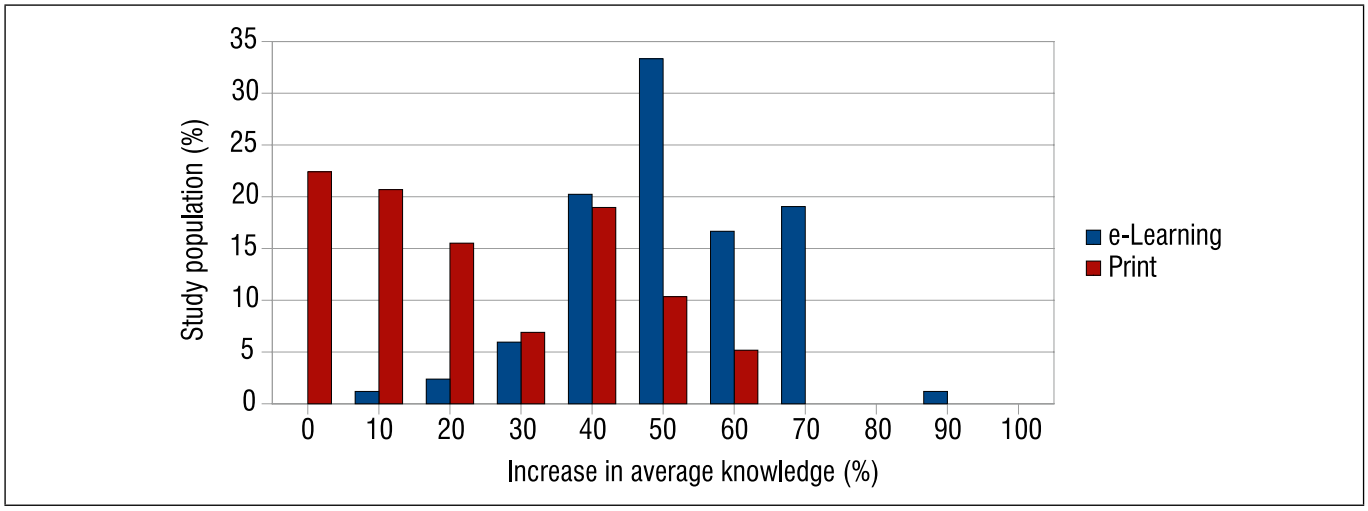

Fig. 5. Average individual knowledge gain during an e-learning and a print-based CME-accredited course. Reproduced with permission from Peter Henning (Karlsruhe University of Applied Sciences, Germany).

the opportunity to work in small groups to solve a CME scenario, and were specifically asked to think strategically about the subject matter. Wyatt presented the audience with an outline brief asking them, within their groups, to address the issue of how to drive interactive debate on the topic of better management of systemic fungal infection in the intensive care unit. Every group was multidisciplinary in composition – each had representation from a CME body, pharmaceutical company and educational provider or agency.

Following an initial presentation providing the necessary background information, the delegates were given 30 minutes to devise a plan to address the issues described in the brief. Most of the feedback presentations had common themes: each group suggested a series of small meetings, the identification of leading experts to steer the meeting discussion and an audience drawn from multidisciplinary team members, including a broad spectrum of treating physicians (all specialties) and a nursing team. One important common factor mentioned by all the groups was that the quality of the education provided, rather than the CME accreditation *per* se, had to be of the highest standard to ensure that the programme was engaging and interactive, and overall, driving a common understanding and vocabulary in the disease area whilst maintaining a focus on patient outcomes.

Wyatt then described the approach that was carried out: a series of practice-based expert exchange meetings involving delegates from over 30 countries, which were consensus-driven using an international and regional faculty that was actively involved in the development of meeting content. These meetings incorporated a combination of interactive case studies, plenary, tutorial and workshop elements. They were structured to engage faculty and a multidisciplinary audience together in group learning, with the focus being on helping drive change in clinical practice at a local level to improve patient outcomes. The meetings were accredited by EACCME. It was interesting to note that even at the end of the session, with much discussion of the data and information, the supporting organisation of this CME activity was not identified, or deduced.

Jörg Ansorg also presented a CME case during the first day of the meeting: an e-learning system called e-CME Center from the Professional Board of German Surgeons, which has now been operating for 6 years. Ansorg described how the system has grown steadily in user numbers to 15,000 members in 2008, and offers a series of blended learning in which users engage with the education in a number of formats – interactive education online, as well as support with text, virtual lectures, online tutorials and other online interaction. The key is that the learning is self-paced and, as the learning progress is monitored, there is a lot of flexibility for the learners to study when it is convenient for them. Ansorg acknowledged that there are disadvantages with e-learning, such as the lack of social contact and a reduction in the ability to interact with one's peers, and that reading and learning on-screen are not ideal. An annual fee allows the user to access over 500 courses online and its use is being taken up by related professionals such as anaesthesiologists and gastroenterologists; due to the common language, cooperation is also available with Austrian and Swiss surgeons. The rate of requests for CME certificates has risen quickly in recent years demonstrating its increasing popularity, especially in light of technological advances allowing for much faster connectivity, and flexibility with different media and functionality.

The meeting concluded with a series of short presentations of further examples from CME-accredited activities. Juan de la Fuente presented a concept currently running in Spain where, as the publisher of *Current Opinion in Psychiatry*, Wolters Kluwer Health are expanding on selected parts of the content, developing a concerted e-learning programme directed at GPs. The aim is to encourage GPs to keep up to date with mental health matters and to reinforce their role in the diagnosis and treatment of psychiatric disorders. The programme

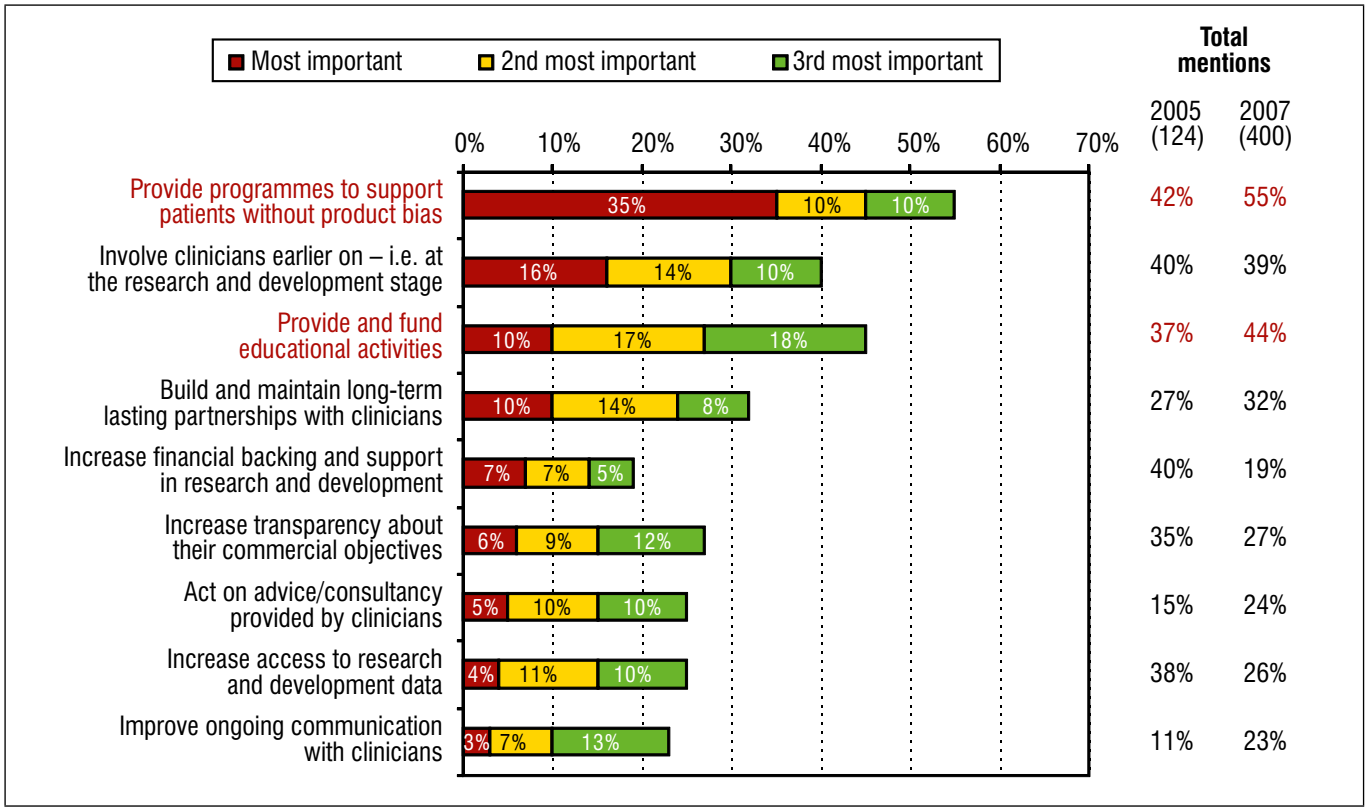

Fig. 6. What activities do you believe pharmaceutical companies should do more of? Reproduced with permission from Emma Sergeant (Ogilvy Healthworld, UK).

is run under the control of a Chair from the University of Alcalà and a number of experts, with Wolters Kluwer Health acting as the Secretariat. It is made available to 50 doctors at a time and runs for a calendar year, with the learners working through a series of modules based on journal articles and taking part in online discussions with experts. Learners also develop research projects, from which one is selected for publication in a supplement to the main journal, and take a final online test. The complete programme is accredited by SACCME for 14 CME credits and the physicians who successfully complete the course and online evaluation receive an 'Expert Degree Diploma' from the University of Alcalà as certificated evidence of participation. The programme is about to complete its first year and the participants for 2009 are already selected.

Dr Peter Posel (QUAIME AG) described the 'NTD Project' for neurologist networks in Germany, initiated by QUAIME AG and based on a structure validated by the QUAIME pilot study. He detailed the objectives of the 3-year CME programme: as well as having clear objectives to improve patient care and to close the educational gap between the knowledge level of GPs and specialists, it also aims to garner greater participation from the learners by having them drive the development of the curriculum itself.

The process is one of continuously presenting the learner with new cases, with a new section made available every 2–3 months, which can be worked through in a variety of ways, all online. The platform offers the learners the opportunity to learn about related topics, including soft skill areas that they may not normally encounter in the usual CME settings. The education is provided online through a mixture of channels so that the participants' various learning styles are catered for: interactive online cases for self-paced learning; 'online seminars', which are limited to 15 participants to maximise the learning experience; and a 'virtual classroom' where the learners decide who they would like to present and on which topic. The areas covered and the structure are driven by an ongoing needs analysis, including a series of pre- and post-testing of the learners, and cooperation from the learning community, under expert guidance. Posel commented that he expects that there will be comprehensive quantitative data to present in a year's time.

CME accreditation of satellite symposia has been a contentious topic for some time, with some CME bodies refusing outright to accredit them, and others doing so only with strict controls. Michelle Turner (Wolters Kluwer Health, UK) described some of the problems that her agency encountered while trying to organise two satellite symposia at the 2008 annual congress of the European Association for the Study of Diabetes (EASD) in Rome. The two symposia were supported by the same two sponsoring companies and were being organised through two offices of Wolters Kluwer Health: London (UK) and Yardley (USA). The supporting company had a choice – whether to hold two traditional satellite symposia as company-run educational events, or to step back and just finance a CME route. In order to achieve some key objectives for the programme – and to clarify the position in which it was likely that the

speakers may want to discuss unlicensed products – It was decided to hand over responsibility to the two chairs of the symposia and run the symposia as CME initiatives. Turner described how things started to go awry when it came to timings: there were pressures from the congress organisers to commit to the satellite symposia, yet a clear accreditation route was not established, the expected agreement between the congress organisers and EACCME for accreditation did not materialise and the Agenzia Italiana del Formaco, the nominated Italian CME body, initially insisted on 90 days to approve all the printed materials. As a back-up plan, Wolters Kluwer Health set up a number of alternatives. They used their Milan office, which is an official provider for both national CME (Ministry of Health) and regional CME (regione Lombardia), to accredit the symposia, as well as continuing to liaise with the congress organisers (EASD), who in turn were communicating with EACCME and the Italian Ministry of Welfare. Just as the final deadline was approached, accreditation notifications came through from both EACCME and the Italian Ministry of Welfare. The final result was two highly successful meetings that were CME accredited, which also played a role in the capacity turnout. However, Turner noted, it could quite easily have concluded unsuccessfully, bearing in mind the timelines required by the CME bodies, and the lack of clarity. Ian Starke commented that this was a good example of how apparently minor decisions of CME bodies can have a highly significant impact on the implementation of a CME programme.

Some CME bodies currently refuse outright to accredit satellite symposia; others do so only with strict controls

The final presentation of the congress was given by Geraldine Reilly (Gilead) and concerned a programme entitled 'HIV and the body', which, earlier in 2008, was awarded 'Best Medical Education Programme – Global' by Communiqué in the UK. Reilly outlined how, with recent successful developments, HIV has turned into a long-term chronic disease, with a huge clinical need with regard to the management of co-morbidities, including cardiovascular disease and hepatic disease, especially renal toxicity. She described Gilead's regulatory commitment to ensuring that physicians are aware of these renal management issues, and the challenge for HIV physicians to broaden their knowledge to effectively manage these co-morbidities.

Gilead helped fund the International HIV Forum, and then stepped away in order not to compromise the work of the group. Reilly described how Gilead put out to tender the administration part of the programme and selected an agency that had no existing or prior relationship with Gilead working on promotional projects. What emerged was a programme that helped physicians re-learn aspects of clinical management that they may not have been using until now. In addition, the programme was broadened to include renal physicians, which meant that there was a sharing of knowledge between the two groups, helping the HIV physicians learn more about the kidney and the renal physicians learn more about treating this emerging patient group. The international meetings were CME-accredited by EACCME, which everyone saw as reinforcing the validity of the programme, and put Gilead in a positive light by demonstrating their financial support, yet enforcing the independence of the programme. Reilly also noted the added enthusiasm of the faculty within the CME structure, as they felt more ownership of the programme and could see the direct benefits of the programme. Reilly concluded that with clear outcomes being visible from the programme, there is now greater routine monitoring of renal function at baseline and not just when problems start and, with Gilead's long-term commitment, the faculty has been motivated to extend the programme to other areas. Support for educational initiatives in the areas of metabolism, liver, bone and heart is now in preparation and will be delivered in the coming months.

Conclusion

The variety and broad range of speakers at this first annual meeting of the European CME Forum outlined the complex situation of CME in Europe. To a newcomer, European CME may have seemed like an area that was still full of confusion, contradiction and uncertainly. But the meeting clearly demonstrated a congruence of thought with a desire for collaboration and sharing of ideas and best practice.

Quis custodiet ipsos custodes?

Edwin Borman used this Latin phrase ("Who will guard the guards?") to illustrate the fact that many CME bodies are in a position where as "policemen" they can only be policed by themselves. Self-policing was shown to be an important role within each stakeholder group and was clearly demonstrated throughout the meeting: the pharmaceutical industry self-regulating the way it supports educational initiatives to make it more trustworthy; CME providers aiming for higher standards than the requirements demand so that their education is of more use to the audience; learners knowing themselves when a piece of education is of true value to them and addressing a specific educational need (hence the support of 'self-accreditation' in the UK). This Latin phrase is commonly used when referring to the *balance* of power within a society or group, rather than to who wields ultimate power. It is by maintaining a mutually beneficial equilibrium, through ongoing discussion and debate, that a satisfactory medium is stabilised. The future of European CME will depend on how its stakeholders come together and interact; it can be more dictatorial (with strictly enforced mandatory CME, government-controlled education and serious punitive

measures for those failing to comply with the rules) or more democratic (voluntary CME and individualised needs-based education that is controlled by the learner with guidance from the regulators). CME systems from across this spectrum were described at the meeting, and others can be seen across the globe.

The future of European CME will depend on how its stakeholders come together and interact

Currently, in Europe there is an abundance of guidance and regulations to ensure that CME is ethical, and it is important for discussions to continue to bring these all into line to offer unified guidance. A clear message that emerged from the meeting is the rising influence of the learner, who is now becoming increasingly involved in the CME process and, with more widespread engagement as well as the ascendance of e-learning, progressively empowered. The learners will become the final arbiters of CME – and the European CME community will need to examine much more closely what makes CME more engaging, of higher quality and more relevant to the learner, and how it can be put into practice.

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Further reading/ online resources

Further information can be found at the European CME Forum website: www.europeanCMEforum.eu

Websites of ESABs and related medical organisations

Academy of Medical Royal Colleges www.aomrc.org.uk

Accreditation Council of Oncology in Europe (ACOE) www.acoe.be

Association of the British Pharmaceutical Industry (ABPI) www.abpi.org.uk

European Accreditation Council for CME (EACCME) www.eaccme.eu

European Accreditation Council in CNS (EACIC) www.eacic.org

European Association of NeuroOncology (EANO) www.eano.eu

European Board for Accreditation in Pneumology (EBAP) www.ebap.org

European Board of Accreditation in Cardiology (EBAC) www.ebac-cme.org

European CanCer Organisation (ECCO) www.ecco-org.eu

European Federation of Pharmaceutical Industries and Associations (EFPIA) www.efpia.org

European Union of Medical Specialists (UEMS) www.uems.net

General Medical Council (GMC) www.gmc-uk.org

Royal College of General Practitioners (RCGP) www.rcgp.org.uk

Royal College of Physicians (RCP) www.rcplondon.ac.uk

Royal College of Paediatrics and Child Health (RCPCH) www.rcpch.ac.uk

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Increasing Transparency in Pharmaceutical Marketing Communications: the new code from the European Federation of Pharmaceutical Industries and Associations (EFPIA)

A KeywordPharma **Expert Review** by Joan Barnard, Rene Lai and Andrew Robson — Published February 2008

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A line-by-line summary of all revisions, both major and minor, to the latest EFPIA code, offering insight into the likely implications for the pharmaceutical industry and its customers.

Executive Summary

The representative body of the pharmaceutical industry in Europe, the European Federation of Pharmaceutical Industries and Associations (EFPIA), issued the latest revision to its code of practice in late 2007. The EFPIA code, introduced in 1992 and last revised in 2004, does not act as a pan-European code, but is implemented through the national codes of its member organisations. The updating of these national codes in line with the new EFPIA guidelines will be completed by the end of July 2008.

Prompted by a desire to answer growing criticism of the pharmaceutical industry with a robust and effective system of self-regulation, the new EFPIA code aims to foster an environment where the public can be confident that choices regarding the medicines they are prescribed are based on individual merits and healthcare needs. As such, the need for greater transparency in pharmaceutical marketing communications is the main take-home message from the new code, which comprises revisions and clarifications designed to tighten existing regulations.

Despite this, certain aspects of the code remain open to interpretation, while other areas allow for flexibility in implementation.

This Expert Review delivers a line-by-line summary of all revisions, both major and minor, to the EFPIA code, and offers insight into the likely implications for the pharmaceutical industry and its customers. It outlines the background and principles of the new code, looks at how it will work in practice and provides guidance on its implementation.

The Review also includes details of an entirely new, separate EFPIA code, designed to regulate industry relationships with patient organisations.

In both cases, the latest EFPIA guidelines underline an increased desire for clarity and transparency in how the industry interacts with its healthcare customers.

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About the author

Dr Joan Barnard (www.joanbarnard.co.uk) is the author and publisher of 'The Code in Practice', a practical guide to the ABPI Code for Head Office staff, and 'The Code in the Field', a guide to the ABPI Code for Medical Representatives. Both books are now in their third editions and are used widely throughout the pharmaceutical industry.

Joan joined the pharmaceutical industry in 1980 and held various positions in clinical research and medical affairs, both in the UK and internationally, including 5 years as a UK Medical Director. She was a member of the ABPI Code of Practice Appeal Board for 4 years.

Joan set up her medical consultancy in 1994, specialising in the regulation of promotional activity, particularly in relation to the ABPI Code of Practice. She runs regular workshops on the code and provides guidance to a broad range of companies on interpretation and implementation of the code. She is registered with the PMCPA as a conciliator.

Joan can be contacted at: BarnardJo@aol.com

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