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Where Are We Now?

by Eugene Pozniak

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The Changing Face of CME in Europe:

Where Are We Now?

By Eugene Pozniak

Executive summary

The European market for Continuing Medical Education (CME) is heterogeneous. In the absence of a single, overarching regulatory body for CME activity across the region, individual countries are at varying stages of implementation. As such, the accreditation process throughout the continent is a splintered affair, governed by four different types of regulatory authority: National Accreditation Authorities, the European Accreditation Council for CME, European Specialty Accreditation Boards and Accredited Providers.

The attitude to CME differs from country to country. Across Europe, each individual autonomous healthcare system has different requirements and expectations of its doctors. In some countries, CME is mandatory, while in others, it is voluntary. In some, it is neither understood nor recognised. However, even in areas where CME is a legal obligation, enforcing compliance remains a challenge. Incentives and punitive measures, some seemingly Draconian, have been introduced to encourage and enforce uptake, but so far a successful method to police the system has yet to emerge.

Despite such a confusing environment, CME-accredited education is regarded as being important. *The Changing Face of CME in Europe* looks at the current climate, assessing some of the factors critical to a successful CME evolution across Europe. It provides a robust definition of CME and its purpose, and details the wide-ranging activities considered worthy of accreditation. In addition, it offers practical advice on how to develop a CME programme, exploring in detail how pre- and post-activity are as important as the educational activity itself.

Significantly, this Expert Review looks at industry involvement in CME activities, exploring the many pitfalls and benefits. The axiom that CME is 'education for doctors, written by doctors, presented by doctors' dictates that there should be no direct industry involvement in specific CME programmes. However, the corporate goodwill derived from being associated with high-quality educational activity, and the benefits of increased therapeutic awareness within the prescribing community, make CME a vital consideration for industry. Whilst it is clear that companies cannot stipulate, manipulate or influence CME content, it is equally clear that companies who fail to support it may somehow be relinquishing an opportunity for competitive advantage.

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Introduction

If you were in the unfortunate position of being stopped by a police officer for an indiscretion, before being reprimanded you would expect the officer to be familiar with the finer points of the law. Likewise, if you spoke to an accountant on a tax matter, you would not be best pleased to be given advice only to find out that your accountant had not read anything on the topic for a year and that tax legislation had subsequently changed. So what of the medical profession? You visit your doctor and present a set of symptoms that leads to a straightforward diagnosis. You would hope to be given the optimal treatment based on the best available evidence. In fact, you would expect nothing less. So how effective are clinicians at keeping up to date with advances in modern medicine? Fortunately, history tells us that they are pretty good and that, although Continuing Medical Education (CME) as a formality is a relatively recent development, doctors have for centuries been conditioned to stay abreast of medical developments. It is part of their job.

At present, health systems across the globe are under increasing pressure as growing healthcare budgets struggle to keep up with advances in treatment and patient care. As technology moves on and clinical practices are developed and shared, the expectations of the medical profession, governments and patients alike have all risen. CME has also, in turn, crossed borders; the ideas and systems that were first seeded in the USA soon after the Second World War, and which have been increasingly formalised since the 1970s, are now spreading globally. Though still very much in its infancy in most countries, CME is seen as a useful tool to enable professionals to quantify how they are keeping up to date with developments that ultimately improve patient care.

As with all modern continuous professional development, the number of stakeholders has increased to include not just the profession concerned, but also the recipients and beneficiaries of the services. In the case of CME, this includes patients, through their representatives (e.g. the government or patient groups), and also the people who fund educational activities: a major contributor to this is, of course, the healthcare industry.

This review examines CME from a European viewpoint, drawing parallels with the more familiar aspects of US CME where appropriate. The aim is to approach each sub-topic with the healthcare industry and their agencies in mind, concentrating on the practicalities, while addressing how the more important theories have emerged.

Eugene Pozniak
November 2007

About the author

Eugene Pozniak is Managing Director of Siyemi Learning, an independent CME provider based in Europe. He has worked in the medical sector for 20 years: following a degree in chemistry, he traced a path through pharmaceutical sales, advertising and medical communications. His introduction to CME came in 1996 when he organised a series of CME-accredited (PGEA) meetings on the newly emerging topic of evidence-based medicine (EBM), coinciding with the publication of David Sackett's influential book on the topic.[1] His fascination with CME and EBM continued until 8 years ago, when, with the growing possibilities in European CME, he finally made the change to working exclusively in CME.

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

In 2006, Eugene founded Siyemi Learning, an independent provider of CME products and related services, assisting medical societies, the healthcare industry and their agencies with national and international CME and Independent Educational projects. Previously he was Director of Global CME (ex-US) at Wolters Kluwer Health.

Eugene can be contacted at: epozniak@siyemi.org

The Changing Face of CME in Europe:

Where Are We Now?

CME in Europe

What is Continuing Medical Education?

There are many definitions of Continuing Medical Education (CME); the topic abounds with acronyms and definitions. From a practical side of things, CME is the continuous professional development that doctors partake in during their professional careers. The Accreditation Council for Continuing Medical Education (ACCME) in the USA describes CME as "educational activities that serve to maintain, develop or increase the knowledge, skills and professional performance and relationships a physician uses to provide services for patients, the public or the profession".[2] In the absence of a European equivalent, the ACCME's definition provides a baseline for analysis within this document.

Looking at a typical career pathway of a doctor, CME is the learning that is done following specialist training (there are formal requirements in place in order to become a primary-care physician or a respiratory physician, etc.), primarily as a way of keeping their skills up to date (Figure 1).

In the absence of more widespread CME, the picture currently looks inversely proportional to what should be happening. Investigations carried out by various European CME accreditation bodies and medical societies into the level of education achieved by doctors during their careers show that once doctors have qualified, and the pressure to pass career-progressing qualifications has eased, their level of learning rapidly drops off.

CME comes in a variety of forms. The term can refer generically to any learning that doctors participate in as part of their daily working lives, or to a mandated requirement for doctors to have certificate proof of having completed X number of CME-accredited activities over a Y-year timescale.

In certain parts of Europe, CME activity is known by other names. For example, in Italy it is referred to as ECM (Educazione Continuada in Medicina), whereas in Spain it is known as FMC (Formación Médica Continuada). In the UK, it has moved from being Postgraduate Education Allowance (PGEA) to Continuous Professional Development (CPD). However, the UK's CPD should not be confused with the CPD that some international organisations are calling for to describe a type of 'CME-Plus', which encapsulates a broader evaluation of physician skills and links them with periodic revalidation or recertification of the doctor.

Clearly, the term CME can, and often does, mean a different thing in different countries. However, the general principles are the same and there are far more commonalities than differences. Put simply, CME can be

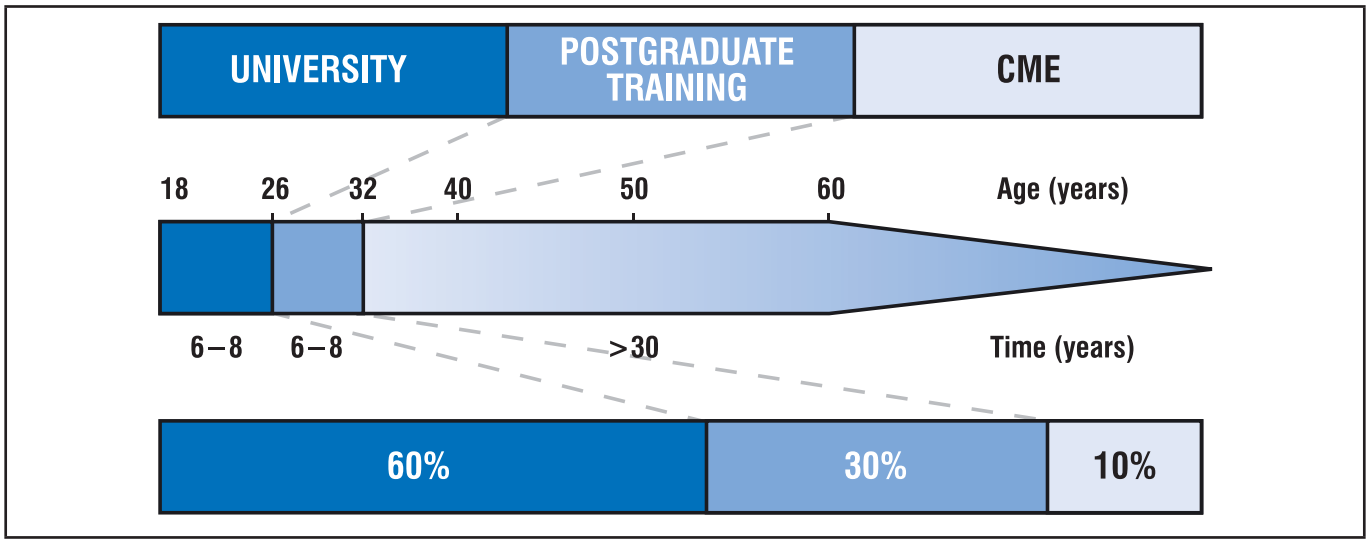

Fig. 1. Medical educational activity over time.

described as education for doctors, written by doctors, presented by doctors.

CME is education for doctors, written by doctors, presented by doctors

What constitutes Europe?

Much of recent European politics has been dominated by the European Union (EU) in its various stages of development and by its guiding principles of common practices and free movement of people and goods across borders. Medical degrees and postgraduate specialist training have come under close scrutiny over time with common practices agreed, through the Directive on Recognition of Qualifications, so that doctors from different EU member countries can demonstrate competency using commonly understood terms and measures, and are free to practise medicine wherever they wish, subject to language skills and available employment positions. CME, however, has escaped the European Commission's attention and so follows the subsidiarity principle – the responsibility lies with individual nations to do what they think is best.

For clarification, this review defines Europe in its most general sense. The EU comprises 27 member states, with additional countries at various stages of accessionary talks. Many businesses consider Europe as simply the original 17 members – for which the full benefits of Union membership exist unfettered – but then also include some non-EU members who are part of the European Economic Area, such as Switzerland and Norway. The Eurovision Song Contest includes Israel as a member of Europe; the European Society of Cardiology has 50 member countries, including Georgia and Armenia, most of north Africa and the near Middle-East; and in some cases when the pharmaceutical sector talks of 'all of Europe' it is most often referring to the five major markets: France, Germany, Italy, Spain and the UK, where the overwhelming majority of sales outside of the USA are realised.

There are additional considerations as CME increases in global importance. Countries that look to practices in the USA or Europe, such as members of the British Commonwealth, or other trading blocs who share educational and training principles and structures, are also adopting similar practices within CME. Much of the information in this Expert Review about Europe can be used equally to clarify CME in other parts of the world.

Accreditation

When considering a CME activity in Europe, there are times where an American, or a European familiar with the US system, may look for something similar to the US ACCME. The ACCME, with apologies for oversimplification, is a body that develops and upholds the standards for CME accreditation in the USA; in effect, it manages the national CME process. The ACCME has its mandate from the government, to whom it is answerable, through the Senate and various government departments and offices. The ACCME accredits and controls a number of CME Providers (there are about 2000 nationally accredited CME Providers) that can accredit educational activities for CME according to the directives of the ACCME.

Unfortunately, a European ACCME equivalent does not currently exist. In fact, the process for accreditation in Europe is an incredibly splintered affair with many different possible routes open for accreditation, each with its own background and history of development, and different levels of authority. However, the CME-accrediting organisations can be grouped into four categories:

1. **National Accreditation Authorities** exist in all the major countries and all have considered CME. In the countries where CME exists, these bodies have responsibility for CME and have systems in place for reviewing and accrediting educational activities. Some are responsible for keeping a record of doctors' progress. Some national systems are still run by medical specialities through the national medical societies and/or universities. Where multiple systems exist there tends to be a nationally agreed 'standard' for accreditation in that country.
2. **European Accreditation Council for CME** (EACCME) – this is not a European body with a similar remit to that of the ACCME, but a part of the European Union of Medical Specialists (UEMS) with responsibility for CME. The EACCME reviews programmes as accredited by a national accreditation authority and grants them wider recognition across other member countries in Europe (within the EU) but does not actually accredit activities itself; the EACCME thus describes itself as a 'clearing house for European CME credits'. The EACCME also acts as a negotiating body, working towards the mutual recognition and harmonisation of CME across Europe, proposing its own European CME credits, or ECMECs, as a standard across the countries where it is active. However, negotiations across Europe are a protracted process and, with national systems still a distance from being mutually compliant, agreements are likely to take years to reach. Currently, CME accreditation is only considered for live events once they have been accredited by a national or specialist accreditation body. The EACCME is currently liaising with national bodies to look at accepting other forms of education, such as e-learning, journal articles and other enduring materials, at some stage. It recently agreed a reciprocity agreement with the ACCME for the mutual recognition of ECMECs and AMA PRA Category 1 Credits™ (the credits assigned by

ACCME-accredited providers), but just for meetings at the moment.

3. **European Specialty Accreditation Boards** are society-led initiatives that offer CME accreditation that can be used by medical professionals across Europe and beyond. They work within the quality guidelines set down by the EACCME, to accredit the congresses of their allied medical society. Some go further and ensure recognition for delegates from the USA, and many also offer the healthcare industry the opportunity to have satellite symposia CME-accredited (with strict guidelines that must be followed). Some accredit additional educational outputs, such as the European Board for Accreditation in Cardiology (EBAC), which has systems in place for accrediting e-learning. EBAC and a few other European Specialty Accreditation Boards also offer journal article CME, usually limited to peer-reviewed journals of national or European medical societies. European Specialty Accreditation Boards also work closely with the related national medical societies (or national chambers) to help develop CME guidelines and services.

4. **Accredited Providers.** This approach is based on a US model in which the organisation developing and presenting the educational activity is accredited, and the organisation follows its own rules and regulations to accredit the actual activity. It acts under the authority and control of the CME authority. At the moment it is possible, in theory, for a provider in Europe to become an ACCME-accredited CME Provider and offer AMA PRA Category 1 Credits™. The regulations are very strict and only a teaching hospital or university, or an existing CME accreditation body is likely to fulfil the criteria for participation. There is currently much speculation that accredited providers will be granted by national bodies in some European countries, such as France, Italy or Spain, in 2008 or 2009. However, it remains to be seen how this will be finally enacted.

European CME-regulating authorities can be grouped into four categories

What is the status of CME in Europe?

Where is CME mandatory?

European countries are at different stages of implementing CME systems, where they have chosen to develop them. They also have different requirements and expectations of their doctors. A regular question asked when discussing CME in Europe is: where is it mandatory? However, information on the subject is limited. To help answer the question, a systematic review, carried out by the author, of 36 European countries, where autonomous medical systems that are in a position to develop CME exist, set out to examine in which countries CME was mandatory.

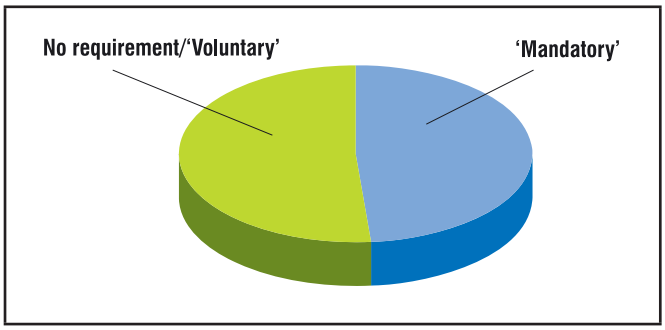

Fig. 2. Country requirements for CME (n=36).

At face value, CME is mandatory in about half of Europe (Figure 2). However, looking deeper into the actual definitions and what the incentives or consequences are of whether CME is done or not, a more complex picture emerges (Figure 3).

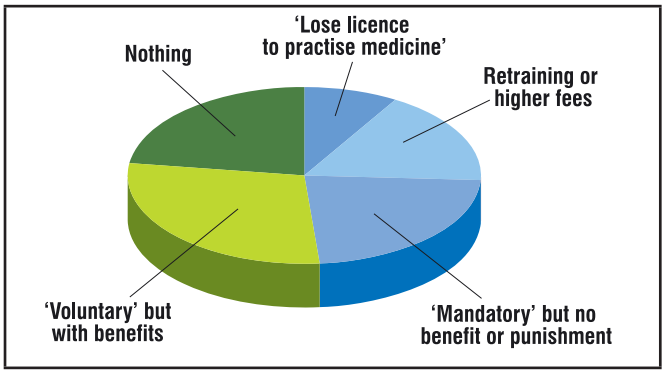

Fig. 3. Incentives and punitive measures (n=36).

There are no conceptual problems in countries such as Albania or Belarus, where CME is neither counted nor recognised, and doctors simply continue to keep up to date as they have always done. However, flaws start to emerge when following-up the countries which state that CME is mandatory. Here, definitions become blurred. For example, in France, CME is mandatory: for over a decade it has been a legal obligation for doctors to do CME. But, until last year, no individual or governing body had responsibility for, or authority over, CME activity. In January 2006, however, the French appointed an individual with responsibility for CME. As a result, CME is now progressing and it would appear that the French are committed to implementing a national CME model in the coming months. A similar situation exists in Poland, where CME is mandatory, but with no workable system as yet in place.

In other countries where doctors are duty-bound to do CME, the situation is still not straightforward. In 2002, the Netherlands completed its first foray into mandatory CME, having implemented a 3-year cycle of CME activity involving around one-third of its doctors. The Dutch had

promised strict guidelines and said that any doctor not fulfilling their obligation by successfully collecting their CME points would lose their licence to practise medicine. The results, however, disappointed the CME community in Europe. These were presented in the form of a simple press release disclosing that, following the 3-year cycle, the government *estimated* that *about* 80% of doctors had fulfilled their CME obligations. Clearly, the threat to withdraw licences was not enacted and, in light of the proven difficulties in imposing such consequences, the Netherlands withdrew their threats; a less Draconian 'mandatory' system is now in place.

CME used to be mandatory for all doctors in Hungary. Until recently, all doctors were expected to work towards collecting their 250 points over a 5-year period; however, there were simply not enough CME programmes for hospital doctors to go to, and added to this was the problem of hospitals not allowing the doctors study leave. Doctors also had to pay all their own expenses, with no tax breaks. The system became unworkable and, following a protest by hospital doctors, CME is now voluntary, although primary-care physicians are still under the threat of formal re-examination if they do not satisfy their CME requirements.

The first modern-day example of European CME took place in the UK in the 1990s. The government, through the Secretary of State for Health, deducted £2000 from GPs' salaries and replaced it with a payment of the same amount if GPs fulfilled CME criteria. At the time, this was known as the PGEA. The system has subsequently changed a number of times. Currently, a mandatory system exists through which all doctors are expected to participate in CME (called CPD). In theory, if a GP does not demonstrate evidence of sufficient CME during his/her annual appraisal, the Appraiser – a representative of the GP's employer, their Primary Care Trust (PCT) – would have grounds to report this to the PCT. The PCT, in turn, has the power to withdraw payments to GPs (which they receive for seeing their patients), investigate and even suspend them. For secondary-care physicians there are other options open, such as the withdrawal of membership of their professional medical society (e.g. Membership of the Royal College of Obstetricians).

But all of these recourses are only theoretical. In the absence of a national CME accreditation body in the UK, it is possible for a physician (especially a GP) to have satisfied their CME requirements without obtaining a single CME certificate. This is because of the diverse range of activities that are considered to constitute CME. These include:

- subscriptions to journals
- practice meetings
- setting up specialist clinics
- background reading.

The UK system has been further complicated by the regionalisation of the NHS, through which each PCT has the authority to interpret or even amend any rules as they see fit. The UK awaits the next stage of what is becoming a multistaged reform of the health service; whether the promised link of CME with revalidation will come about remains to be seen.

In Belgium, where CME is 'voluntary', a physician can increase his/her fees by up to 5% if he/she keeps up with CME – a much stronger incentive to do CME than under most 'mandatory' systems. In Italy, on the other hand, CME is mandatory, but there is no formal incentive scheme or punishment for failure to comply. In Spain, Portugal, Sweden and other parts of Europe, CME is voluntary, but doctors' employers or insurance companies expect them to be able to prove that they have been keeping up to date with their CME.

In Belgium, where CME is 'voluntary', a physician can increase his/her fees by up to 5% if he/she keeps up with CME

With such a heterogeneous system across Europe, it would be easy to point to the mandatory system operated in the USA as the blueprint for success, the perception being that doctors failing to satisfy CME requirements will not have licences to practise medicine renewed. However, further examination shows that while the ACCME has control over 52 states – the 50 states of America plus Puerto Rico and Guam – CME is mandatory in only 40. Despite this, doctors appear to carry out CME in all states and territories, as, even if it is not mandatory, there are benefits such as lower professional insurance premiums or employer expectations or requirements. Nevertheless, even in the USA, where the perception is that CME is mandatory, this is not quite the case.

Despite the confusing system in Europe, CME-accredited education is regarded as being important. Expectations for its use are high, and mandatory CME is not necessarily as Draconian as it sounds. In fact, to date, not a single doctor in Europe has lost their licence to practise medicine from not satisfying their CME obligations. CME can only be truly 'mandatory' if there is some kind of punishment that can, and is, carried out. Bizarrely, it seems that many of the voluntary systems are more compulsory than the mandatory ones. Mandatory CME seems to reflect the situation that is seen with the convention of stopping at red traffic lights: it is more mandatory to do so in Nice or Cologne than it is in Naples or Cairo.

Why do doctors do CME?

With or without an adequate regulatory framework across Europe, the question remains: why do European doctors actually carry out CME activities? Ongoing education during a physician's working lifespan is not something new; doctors have been doing CME like this as part of their jobs for years. The earliest example found in the

literature is from the city-state of medieval Florence where city officials, concerned with the consistency of medical care for its population in a time of rapidly growing knowledge, insisted that all practising physicians had to attend an annual refresher meeting to learn about latest clinical practice.[3] There is no doubt that there are many doctors who have managed to avoid any kind of increase in knowledge during their working lives over the years but, on the whole, doctors are professionals who take pride in their own work and, as such, feel it an ethical obligation to maintain their knowledge levels so that they can best serve their patients.

Doctors are professionals and feel it an ethical obligation to maintain their knowledge levels so that they can best serve their patients

One of the reasons why fully mandatory CME with punitive measures is struggling to take hold in Europe is simply because there is little evidence to show that forcing doctors to do CME actually works. In the words of Plato: "no study, pursued under compulsion, remains rooted in the memory".[4] Bernard Maillet, Secretary General of the UEMS, with responsibility for the EACCME, says that CME should be an ethical compulsion of the individual and that "mandatory CME is not effective in the weeding out of bad apples".[5] To prove the point, the infamous British GP Harold Shipman was up to date with his own CME requirements.

The mandatory versus voluntary question is therefore a red herring as far as doctors, the industry and other supporting organisations are concerned. For centuries, doctors have strived to keep up to date. In the modern climate of increased scrutiny of the profession, close examination of what drives a doctor to engage in formal CME may show an element of 'point collecting' to satisfy requirements. However, most doctors far exceed any obligated requirement without a 'carrot' or 'stick'.

What constitutes a CME activity?

In Europe, there are a number of types of CME activity that can currently be accredited for CME.

Meetings: All the CME accreditation bodies accredit meetings of some sort. Under current regulations the meetings can be either satellite symposia to the congress of a medical society, or a meeting held at an educational institute such as a teaching hospital.

e-learning and educational DVDs: A small number of CME accreditation bodies accredit these computer-based distance learning outputs.

Print articles: Once again, a few bodies accredit print articles. These tend to be limited to single articles in peer-reviewed journals, and then usually the official journal of a medical society.

In the USA, many more types of activity can be accredited: for example, chapter reprints from textbooks, activities on a personal digital assistant, even medical wall posters. The outputs that are acceptable for accreditation are clearly defined by the relevant CME accreditation body, which specifies the rules that need to be followed. Whatever the style of educational activity, however, there are core principles that apply to all CME activities and these can be grouped into three distinct areas (Figure 4).

Each CME activity needs to be preceded by some kind of planning process and preparation, involving the selection of experts, content development and organisational aspects of the project. Then there is the educational activity itself, followed by a post-education period to complete the CME process, gain feedback and finally acknowledge the participation of the learner with a certificate.

Pre-activity

There are a number of processes that need to be worked on in a concerted fashion in the development of a CME activity: planning, preparation and the accreditation itself. Many of the formalities surrounding this activity

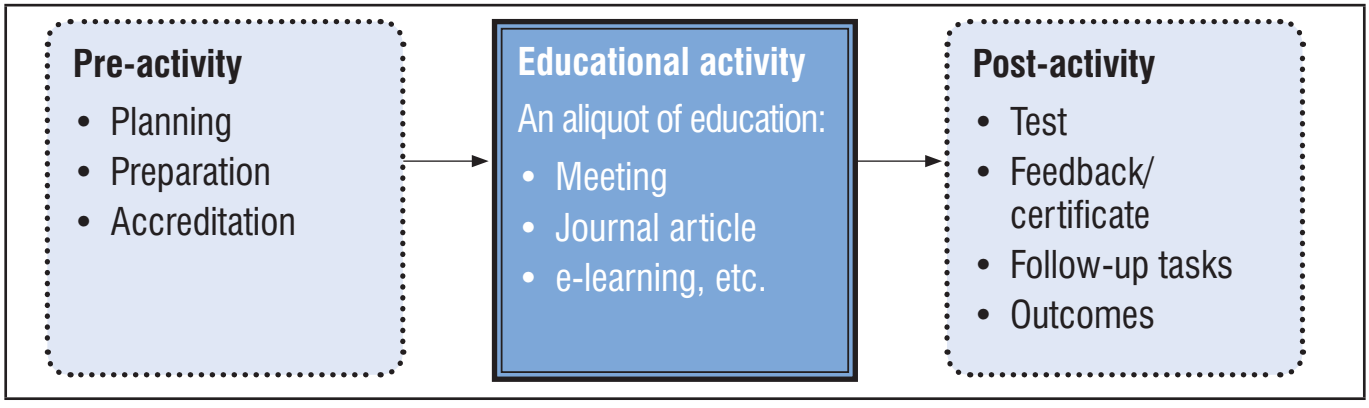

Fig. 4. The CME process.

will be determined by the CME accreditation body, the requirements of which will need to be followed and complied with.

The initial planning process requires consideration as to why the education is being developed and what the overall aims are for the educational activity. As part of the accreditation review process, most CME accreditation bodies require full documentation clarifying the needs analysis. This documentation should include:

- the identified reasons for the activity
- details of how the activity is going to be planned and implemented
- the expected outcomes
- predefined learning objectives.

From this documentation, the target audience can be derived, and a faculty of experts with the relevant experience and prestige selected. There is also an increasing trend now in Europe to reflect the US practice of identifying and resolving any potential conflict of interest with people involved in the educational activity.

The scientific programme and educational content should be developed by the faculty

The scientific programme and educational content should be developed by the faculty. It is acceptable, and encouraged, to develop innovative presentational techniques to ensure maximum knowledge transfer, but there is a lot of sensitivity surrounding 'ghost writing' or offers of 'checking for accuracy'. The experts have been selected to fulfil that role, and CME accreditation bodies are clear in the direction that they give to ensure the independence of the activity they are accrediting. It must be remembered that where an educational activity is "supported by an unrestricted educational grant from Company X" these words have been carefully selected and that:

- 'unrestricted' has far-reaching consequences for the CME activity
- it flags it up as educational activity independent of any control other than by the faculty itself
- significantly, the supporting company has relinquished control over the programme.

Once the educational activity has been developed it needs to be checked for accuracy to ensure that the messages are consistent with current medical opinion and are evidence based. This means an independent peer-review process, with two or more expert peers who are independent of the activity. While a strict requirement in the USA, some CME accreditation bodies in Europe do not have this as a formal step as yet, but it is good practice to include it, nevertheless.

Once enough of the educational activity has been determined, as in the case of a meeting, or the enduring material has been fully developed, then the formalities with the relevant CME accreditation body can be progressed so that it can be reviewed and accredited in time for the learners to take part in the educational activity.

Educational activity

As the box in Figure 4 shows, this is the hermetically sealed part of the whole CME process. Core to the CME activity is the aliquot of education, an exactly measured chunk of predetermined and pre-approved educational activity – once approved, it is invariable and untouchable.

A CME credit from an accrediting authority will have an exact value, depending on the type of activity. For example:

- meetings must be a specified 55 minutes per credit
- journal articles must be at least 4500 words with a test of eight questions (and a pass mark of 6) at the end, or
- a minimum of 20 computer-screen views that would take a reader over 40 minutes to read and interact with.

Each accreditable activity is clearly defined by the authority. Once the programme is developed and presented or described to the CME accreditation body, it can be changed only with written approval. This means that no non-approved materials or messages can be included (or slipped in). So if, for example, the accrediting authority allows local representatives to escort doctors to a CME meeting, such representatives cannot influence what goes on at the meeting. Likewise, the subtle distribution of leaflets sporting drug brand logos or invitations to a lavish dinner afterwards is similarly prohibited. The meeting is run by the faculty and only their educational messages can be presented and only predefined interactions can take place.

Post-activity

Following the CME activity the learner needs recognition of their efforts, and formalities with the CME accreditation body have to be concluded. If the accredited activity was not a meeting (where there is physical proof that the person took part) then the learner will be expected to take (and usually pass) a test. In Europe this is used more as a proof of participation rather than a test of knowledge or a measure of educational outcomes. Feedback on the quality of the education and whether any bias was evident is the final requirement of the learner before a certificate is issued, as specified by the CME accreditation body. Evaluation of the learning experience is crucial in determining the quality of the programme as well as providing guidance for the development of future programmes. Direct feedback from participants is closely scrutinised in the USA, and increasingly so in Europe. The educational cycle can then be continued as this feedback is fed into the needs analysis of future activities. The concluding formality with the accrediting

authority usually involves the provider or organiser of the educational activity sending to the CME-accrediting body details of participants with dates and the number of credits gained; sometimes further details are required, such as a summary report with interpreted results.

Measuring effectiveness of the education

There is an ever-growing trend to evaluate the effectiveness of education: application in everyday clinical practice of the knowledge and skills gained. Usually, as part of the feedback and evaluation process, the doctor is asked whether they expect their clinical practice to change. This is then matched against the needs assessment and learning objectives. Occasionally, this is followed-up some weeks or months later with further questioning. This post-activity feedback can gauge the level of the doctor's intent to change their clinical practice, but is a poor measure of actual behavioural change. Sophisticated tools have been developed to look at attitudinal shifts and actual clinical practice over time, and match them against the CME programmes in which clinicians participated. The idea behind measuring educational effectiveness is that, through continuous quality improvement measures, a perpetual cycle of continuous improvement and improved physician care can be initiated and driven.[6] This, in turn, feeds the needs analyses and learning objectives of future CME programmes.

Usually, as part of the feedback and evaluation process, the doctor is asked whether they expect their clinical practice to change

It has been shown that different styles of education, as well as the varying quality of educational programmes, have differing impacts on closing the gap between actual clinical practice and Best Clinical Practice.[7] Some CME authorities bear this in mind when reviewing programmes to accredit for CME. For example, Spain uses a weighting system through which proven effective educational styles and techniques receive a higher CME credit rating than less engaging activities. Broadly speaking, it is not yet a major consideration in Europe with CME still in its fledgling state, but in the USA the ACCME has asked providers to employ clearer metrics in their methodologies that demonstrate just how effective their educational programmes are in improving patient care.

How is CME funded?

At the moment it is very difficult to gauge how much CME is taking place in Europe. The disparate nature of CME accreditation across the region, and the absence of formal international systems, means that CME activities can sometimes occur without being widely reported. Added to this are the many unbiased educational meetings that take place unreported, which could be accredited for CME, but currently are not. In the USA, they would be accredited as a matter of course.

On the whole, governments are slow to provide funding and, in some countries, are even reluctant to give tax relief for participants' expenses. Employers, by way of health services, hospitals and universities, currently provide much of the CME, and contribute greatly to their support with study leave and financial assistance. Physicians themselves are very occasionally willing to pay; in Germany this is a matter of course where the strict regulations restrict industry (pharmaceutical companies, medical devices and diagnostic companies) funding of doctor activities.

Medical societies are taking a leadership position in the provision of CME and have their congresses routinely accredited for CME; many offer additional educational programmes. This brings into play the role of industry and its support of the activities of medical societies, whether directly by exhibiting at the meetings or hosting satellite symposia, or indirectly through supporting doctor attendance. Of the 1000 or so meetings accredited by the EACCME annually, they estimate that about 60% are funded by industry. This is in line with US estimates that at least 60% of meetings are funded with industry support.[8] However, it is difficult to quantify the commercial value of these projects.

Medical societies are taking a leadership position in the provision of CME and have their congresses routinely accredited for CME

Industry and CME

What is the role of industry in CME?

On the whole, industry has no role in CME. There are very strict rules concerning industry involvement in CME and many of these have been put in place in order to avoid the pitfalls encountered in the USA, where inappropriate involvement and influence of industry has led to much criticism.[9] Currently the Senate Committee on Finance is querying with the ACCME the issue of commercial bias and the inappropriate influence of industry in CME programmes. As a result of this, the ACCME has been contemplating tightening their already strict rules on CME in order to further separate the source of funding (i.e. the supporting company) and the educational activity. Included in this is the possibility of withdrawing the accredited provider status of companies they deem to be

too close to the interests of industry, such as subsidiary companies of medical publishers and communications agencies.

In Europe, in the absence of involvement of government, this area is governed by the rules of the individual CME accreditation bodies. With a mostly voluntary state of affairs, the rules are tending to be clarified, with a trend towards clearer separation of industry from the CME activity, with loopholes being closed rather than the imposition of stricter enforcement of increased measures. According to the axiom 'education for doctors, written by doctors, presented by doctors', there is no place for industry in this arrangement; however, a related, but different, question can be asked: what can industry get out of supporting CME?

What can industry get out of supporting CME?

There are benefits to being associated with an unbiased educational activity, and physicians are very grateful for high-quality education. By supporting CME, companies can benefit not only from corporate goodwill but also from an increase in trust and personal contact (where allowed). This can lead to further opportunities. But there are other reasons too: while it is clear that companies cannot stipulate what is being covered, CME can create 'noise' in an area of interest to the supporting company and increase awareness among the prescribing community.

CME can create 'noise' in an area of interest to the supporting company and increase awareness among the prescribing community

But what else can a supporting company hope to get? If a CME activity is planned well and the activity put together appropriately it could be possible to derive some very useful data. A high-quality CME activity can place the learner in a situation where they are relaxed and are considering their own clinical practice. Through setting up scenarios where the learner is taken through key decision-making points, the pathways to final prescribing or buying choices can be elucidated and better understood. Essentially, if the supporting company is content to relinquish the usual level of control of an educational meeting, the added kudos of having an unbiased activity can help move the learner into a more comfortable zone, where, in turn, they are more prepared to give unbiased feedback.

On the negative side, supporting CME cannot be evaluated through traditional return on investment (ROI) metrics, which would invariably involve scrutinising sales figures and market share. Such an attempt would prove that the education is inherently biased – and the education that would score highly in this type of ROI calculation would be of low educational value to the doctor, thus negating supporting this activity in the first place. So other markers, direct and surrogate, have been devised and are used. The objective is to have a meaningful way of quantifying the knowledge gained as a result of the educational activity and its affect on the clinical practice of the physician. However, even the newly emerging calculations of return on education investment (ROEI), borrowed from academia and increasingly used in US CME settings, do not translate well to European CME. Matching internal activity against measures of educational effectiveness and outcomes can give the supporting company a good indication of how well their financial support has been used and can help future decisions on what types of activity to support. But, on balance, supporting CME is a high-quality activity that a company often considers when it is in a market leader position – where all tactical promotional routes are already actively engaged and routes are being examined to increase the corporate goodwill.

What does the future hold for CME?

CME in Europe is growing annually at a steady pace (Figure 5). From its humble beginnings at the turn of the century, the level of accreditations each year is running into the thousands. It has been a slow and steady progress, but CME has now crossed the Rubicon and has the rapt attention of all stakeholders: professionals, patients and industry.

CME in Europe is growing annually at a steady pace

The benefit of having a steadily emerging CME scene in Europe is that the rules are being created through organic growth, with much discussion and debate. Progress occurs in a series of productive forward steps. The future will be mapped by a journey towards closer working practices, mutual recognition of credits and harmonisation of systems. As these systems develop there will be careful examination to ensure that industry keeps a meaningful distance: close enough so that it receives sufficient benefit for financially supporting educational programmes, but far enough to maintain the credibility of the education through visibly distancing potential sources of commercial influence and bias.

Whether CME moves towards assuming a role in the revalidation or recertification of doctors or just becomes more 'mandatory' remains to be seen. However, this is an issue that resides outside the sphere of how far industry and other organisations will be prepared to support CME. The main attraction is the stamp of quality that CME accreditation brings to education for doctors.

Medical societies and their partner CME accreditation bodies are increasingly involved in the drawing up of

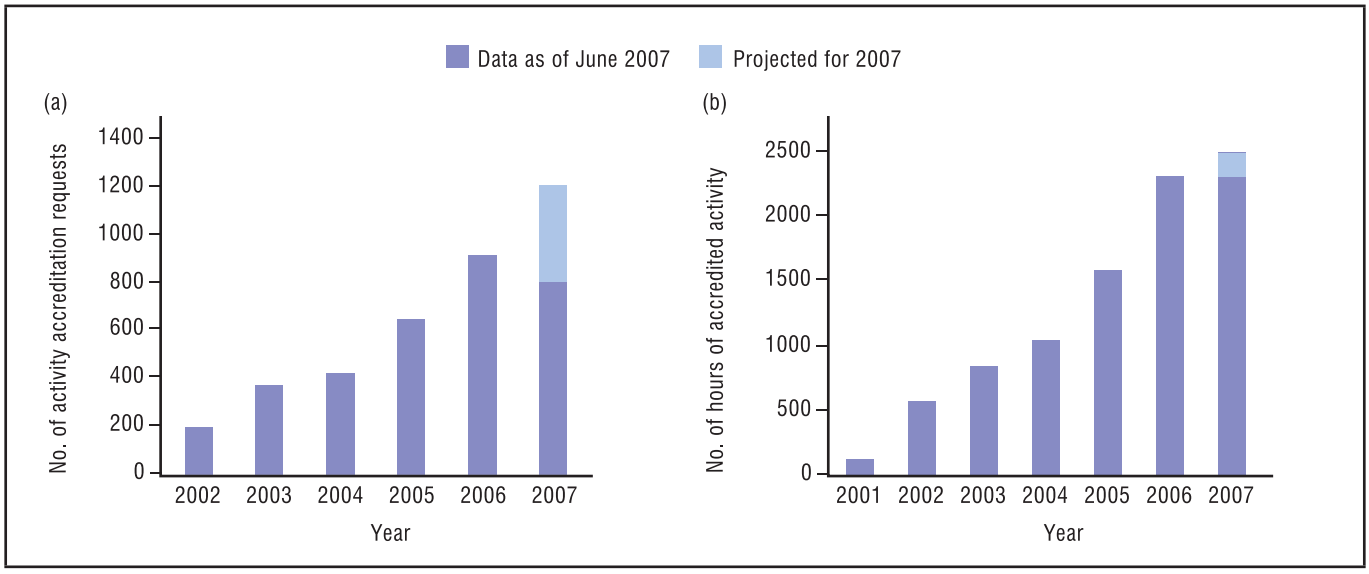

Fig. 5. Annual (a) EACCME and (b) EBAC accreditations. (a) Adapted from Maillet B. Presented at the Symposium on Globalisation of CME/CPD during the Association for Medical Education in Europe (AMEE) Congress. Trondheim 25–29 August 2007; (b) adapted from www.game-cme.org

curricula for what specialists should be keeping up to date with, and are looking to add more educational support to their existing portfolio of services to their members. There may eventually be increased interest from national governments and even the European Commission (who continue to offer funding for the evaluation of systems in CME), with the potential for additional budgets to support their interest in public health programmes. Industry, too, is taking note of developments of CME in Europe and the potential benefits of being associated with it. Certainly, the current commercial and CME climate in the USA has meant that educational budgets are increasingly being steered towards supporting European educational initiatives. But, with a maturing CME environment in Europe, and the increasing expectations of accreditation bodies and individual professionals, it is becoming more important for industry to approach CME specialists earlier when planning to support CME programmes – with the tightening regulations it is not possible to 'reverse-engineer' CME into an educational programme.

Conclusion

I hope that this review has elucidated the CME scene in Europe and has gone some way to explaining the feeling that, while supporting CME in Europe may currently have questionable benefits, companies who don't support it may somehow be at a distinct disadvantage.

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Further reading

Accreditation Council for Continuing Medical Education (ACCME): www.accme.org – see in particular the document: *The ACCME's Essential Areas and Their Elements*.

European Accreditation Council for Continuing Medical Education (EACCME), part of European Union of Medical Specialists (UEMS): www.uems.net – visit the EACCME section for information about CME.

European Board for Accreditation in Cardiology: www.ebac-cme.org – valuable document section that gives guidance on CME.

Global Alliance for Medical Education (GAME): www.game-cme.org

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An in-depth report from The International Publication Planning Association's 5th Annual Meeting held in San Francisco, CA, 25-26 June 2007.

Executive Summary

The reputation of the global pharmaceutical industry is currently suffering, and there is public mistrust of drug companies' publication practices. The industry can only eradicate this problem through increased transparency, honesty and openness in its publications. Clearly, the provision of unbiased information to medical decision makers is essential, not only for the sake of the industry's image, but, more importantly, for the good of public health.

In an environment of rapidly changing rules and regulations, pharmaceutical companies must develop their own robust publication policies that reflect the latest guidelines. Crucially, they must also develop compliance programmes to ensure that all those working on publications not only understand company policy, but actively implement it.

This Conference Insights review provides an in-depth review of the 5th Annual Meeting of The International Publication Planning Association held in San Francisco, CA, 25–26 June 2007. It details the major challenges facing publications professionals, including the need for disclosure, transparency and compliance. It offers guidance on how to develop and implement company policy, looks at the involvement of marketing in the publication process, the growth of open-access publishing and how agencies and drug companies can develop effective partnerships.

Contents

About the author

Elizabeth (Liz) Wager is the author of books on '*Getting Research Published: An A to Z of Publication Strategy*' and '*How to Survive Peer Review*'. She is a co-author of '*Good Publication Practice For Pharmaceutical Companies*' and the European Medical Writers Association guidelines on the role of medical writers.

After obtaining a First Class zoology degree from Oxford in 1983 she worked for Blackwell Scientific Publications, Janssen-Cilag then Glaxo-Wellcome. In 2001, she set up her own company, Sideview, which provides training, writing, editing and publication consultancy services.

She is a member of: the *BMJ*'s Ethics Committee, the World Association of Medical Editors Ethics Committee, the Council of the Committee on Publication Ethics, the editorial board of *European Science Editing* (the journal of the European Association of Science Editors) and the World Health Organization Scientific Advisory Group on trial registration.

She can be contacted at: liz@sideview.demon.co.uk or via www.lizwager.com

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