


raising the bar

Initiative aims to set clear guidelines for best practice in European CME



Developments in European Continuing Medical Education (CME) are gathering pace; there are now meetings dedicated to it and CME is increasingly attracting the attention of pharma companies and regulatory bodies. Also, the volume of articles published on it in the European pharmaceutical trade press has multiplied several times over in the past 18 months. This article examines what has contributed to this change and how the situation in Europe is progressing.

In the past, those involved in CME in Europe looked to the US for guidance. Anyone familiar with accredited medical education and CME in its modern form will be conversant with the system in the US, especially the main channel used for commercially supported CME, run by the Accreditation Council for Continuing Medical Education (ACCME). They will also be aware of the 'problems' that have been widely reported in recent years.

Negative press in US CME seems to run in three-yearly cycles. There, when something is

found, everyone reacts and must be seen to react. A pendulum is pulled back hard and let go to swing; extreme, unsettling changes are made and pharma stands frozen in the headlights of a threatening regulatory juggernaut for a few months. With each successive wave of changes, the pendulum swings even higher, rather than being brought to rest in peaceful equilibrium.

Over the past five years or so, the pendulum has been prevented from coming to rest, creating an environment of change and uncertainty. This is partly as a result of the 2003 guidance from the US Office of Inspector General (OIG), insisting that CME funding could not come from marketing teams in the pharma companies, and the reflection in the agency sector whereby companies involved in promotional work have been, *de facto*, excluded from working in the CME arena. The one inevitable result has been tighter control over any influence industry has in CME, other than continuing to fund it.

“One effect is a move away from the perception that CME is something US-led that the rest follow”

One indirect effect of these developments is a move away from the perception that CME is something US-led that the rest of the world follows.

Now, CME in Europe is developing a character of its own. It is not easy to give a brief overview of the differences, but as someone with a more legal mind once explained: one continent lives by the maxim that “what is not forbidden is allowed”; the other lives by “what is not allowed is forbidden”. In the US, this gives rise to paperwork and regulations extending to hefty tomes of unintelligible copy, while the European versions have a few pages of clear language, but with limited detail.

It is possible to access textbooks on how to work in CME in the US, yet this level of guidance is lacking in Europe. Or is it? The depth of literature may not be there, but the broad principles are in place. European ‘rules’ are taking shape and even converging. The accreditation arm of the European Union of Medical Specialists, the European Accreditation Council for CME (UEMS-EACCME) is driving some new quality initiatives, working closely with the European Speciality Accreditation Boards (ESABs) and the member National Accreditation Authorities (NAAs) in airing issues that affect the relevance and credibility of educational programmes.

Even the NAAs and ESABs that are not part of the UEMS-EACCME structure look to them, as well as to each other, to gauge the standards

prevalent in Europe, and adopt largely similar principles. In the decade or so of formal CME, the ‘rules’ now look largely familiar across all the accreditation bodies, even though there are more than twice as many accreditation bodies as there are countries in Europe.

This also means that CME bodies are also moving on from working out ways of policing a system to more advanced discussions, such as how they can guide education providers to improve the quality of the education they develop for their target audience. There is increasing focus on the usefulness of education to the learner and the eventual benefit to patients.

PHARMA FUNDING

A key factor in the success of CME is the level of funding. CME in the US grew at a staggering rate with the help of commercial support. With recent developments, new rules incorporating stricter criteria to keep pharma involvement even further from CME have led some companies there to distance themselves yet more from activities.

However, the trend emerging in European pharma companies is different. Though some flatly refuse to fund educational activities that they cannot control, thereby removing themselves from the European CME environment, others get involved if there are attractive and demonstrable benefits. Increasing numbers are now embracing CME as a new relationship management channel that is not overtly promotional, to engage with, rather than just communicate messages to, their target audience.

In addition, organisations such as the European Medicines Agency (EMA), the UK’s National Institute for Health and Clinical Excellence (NICE) and Germany’s Institute for Quality and Efficiency in Health Care (IQWiG) are looking at further requirements in their reviews of products. They are asking pharma companies what steps they are taking to promote better education in the disease area concerned and not just about the dissemination of promotional information about the product in question.

LACK OF EXPERIENCE

This requirement pushes pharma activity into new areas in which many have no experience. Clearly, it is not just promotion and raises the question of whether commercial functions should be responsible for funding these educational initiatives and especially CME programmes.

Some companies have moved responsibility under the control of medical affairs, which helps the regulatory sign-off process, with the added rules that need to be followed. However, when these people need to engage the services of an external organisation, many are not familiar with the agency structures that trip off the tongues of many readers of this article. A medical director does not necessarily know what different agencies offer, not having the

experience that those in marketing functions would have had for most of their careers.

AGENCIES

The third stakeholder group in European CME comprises the organisations that provide the education in the first place. Traditionally, this role has been fulfilled by an agency. Mostly this is a medical communications or medical education agency but it can be a PR or advertising agency. In the case of CME, this raises a problem, as the word 'agency' clearly describes an organisation that acts as an agent on behalf of a client. The client is the pharma company and it is well known what tune the piper will be playing, which is unacceptable in terms of CME regulations.

Currently in Europe there are few organisations that can act independently and knowledgeably in CME, even where physicians or universities have set up their own education organisations. In some cases, organisations have internal expertise, but this is usually one individual willing to take charge of, and police, the CME rules in-house and drive a project to completion within the acceptable parameters.

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As CME matures in Europe there will be a need for dedicated 'education providers' that do not act as 'agencies'. These organisations will no longer have 'clients', nor be obliged to operate under the regulatory restrictions of the pharma industry; after all, CME is not promotion. Neither will they be working in a regulatory vacuum, as anyone engaging in CME must follow the rules of accreditation bodies. However, this means the financial supporter has a less controlling role, with the education providers no longer reacting to briefs, but playing a much more accountable role with added responsibilities.

NEW GROUP

While there are clear rules and expectations for the CME bodies and pharma companies, there is little to guide education providers on how to engage with CME. This has led to the formation of the Good CME Practice Group (www.gCMEp.eu), which held its inaugural meeting last November. Its remit is to examine how the European education provider/agency community works in CME, to evaluate what could be considered best practice and to develop appropriate operating standards.

Over a dozen education providers are now collaborating on the details. The members have all developed accredited education in Europe. As

well as physicians and organisations experienced in providing CME education, there are many with traditional 'promotional' backgrounds, from pharma, communications agencies and publishing. The group is working in partnership with the Rome CME-CPD Group, a think tank of individuals from CME accreditation bodies and related organisations across the globe, with significant European representation.

There are also other links with CME accreditation bodies to ensure that the operational details comply with their expectations, as well as with key figures from the pharmaceutical industry to confirm that the resulting work can indeed demonstrate to potential financial supporters that the organisations that adopt these standards are knowledgeable enough to engage with CME to the highest standards.

It is now working to define standards based on the core principles of:

Appropriate education

Where educational programmes should address pre-identified educational needs and be relevant to a specific target audience.

Quality

Education should be of the highest quality, be evidence-based and developed to address specific learning objectives effectively, with quality control systems and processes in place.

Fair balance

Educational programmes should be fair, balanced and free from bias, whether political, commercial, personal, or from any other source.

Transparency

Relevant relationships between individuals and organisations, sources of funding, origins or generation of content, should be transparent.

Effectiveness

Each programme should have an outcomes measurement mechanism to evaluate its effectiveness.

At its spring meeting in London on May 20, the gCMEp Group will develop practical guidance on how each point can be sensibly demonstrated and worked into the education programme development process. Close partnership with the other stakeholders will also make the guidance of value to CME bodies as well as to financial supporters looking for reassurance. It will also learn from developments in the US.

Finally, it will aim to set standards for the newly emerging education provider community to become a visible, credible and active partner in the delivery of high quality CME that will have a measurable and meaningful impact on patient care.

The Author

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