

non-promotional activities and CME

Mounting public scrutiny of promotional activities has created increased importance for non-promotional activities. Are you pursuing enough opportunities for CME?

Traditionally, pharmaceutical companies have used promotion of products direct to healthcare professionals as the mainstay of their marketing approach. However, whilst these promotional activities have been aligned with market authorisations, the industry generally has come under mounting public scrutiny and criticism over the last five years for the ethics and worthiness of some of its activities.

This has led to tightening of the Association of the British Pharmaceutical Industry (ABPI) and European Federation of Pharmaceutical Industries and Associations (EFPIA) Codes of Practice, as well as the development of clinical trials registries and publication guidelines.

Together, these changes have provided new opportunities and increased the relative importance of non-promotional activities which can, at their simplest, be thought of as any activities that do not fall within the 'promotional' definition.

Thus, non-promotional activities do not focus on product, but rather cover areas such as disease awareness and unmet

medical need, although products can still be mentioned as part of an unbiased appraisal of all therapy options.

It is clear from widespread experience in the US that continuing medical education (CME) – educational activities undertaken by qualified doctors (voluntary in some countries but mandatory in others) to maintain and develop their clinical skills – is a non-promotional activity they highly value. Pharma companies in the UK and Europe have varied in their response to the changing European environment, but actions they have taken include (see Figure 1):

- Considering non-promotional activities as an integrated part of the strategic communications mix and building them into tactical plans
- Separating the budgets for promotional and non-promotional activities
- Completely separating the functions and staff involved in these different activities, with promotional projects remaining with the marketing groups, and medical departments given responsibility for non-promotional work.

This response is still evolving in the UK and Europe and is likely to be influenced by additional changes in the US, where regulations are expected to tighten further.

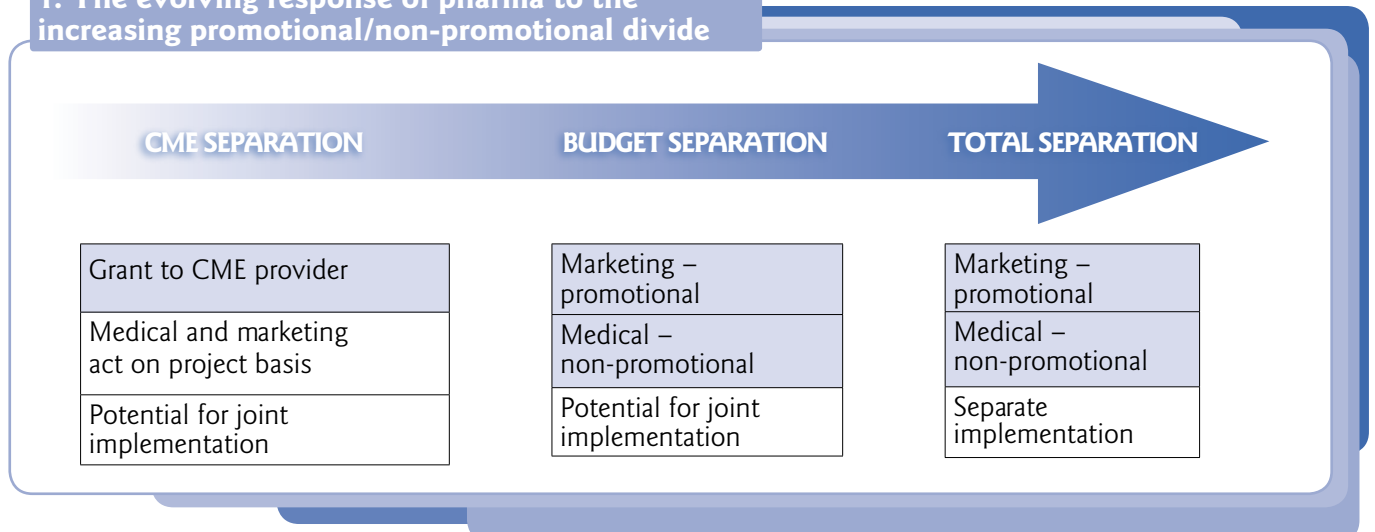
Examples of non-promotional medical education activities include:

- Market research
- Corporate activities
- Press releases (non-product focused)
- Pre-launch communication of new scientific data as part of a balanced programme
- Non-clinical skills training
- Disease awareness activities
- Disease management initiatives
- CME accredited activities
- Meetings
- Enduring materials
- Advisory boards
- Educational grants.

WHAT'S IN IT FOR ME?

So why should you budget for activities where you can't push your key messages? Firstly, products cannot be actively promoted before they have a marketing

1. The evolving response of pharma to the increasing promotional/non-promotional divide



2. When to use promotional or non-promotional approaches

Promotional	Non-promotional	Non-promotional accredited CME
<ul style="list-style-type: none"> • When main focus is on product • When marketing authorisation is in place • When representatives are to be involved • When key messages relate specifically to products • When product differentiation is key • Me-too products • In an established market • To establish KOL relationships 	<ul style="list-style-type: none"> • Education • Pre-launch • Entering a new therapy area • To support a portfolio • To maintain market presence • To raise corporate profile • When focus is on disease awareness/therapy options • To establish KOL relationships 	<ul style="list-style-type: none"> • Education • Pre-launch • Entering a new therapy area • To support a portfolio • To maintain market presence • To raise corporate profile • New mode of action • First/only product in class • Product is already standard of care • Product will perform strongly in a balanced appraisal of treatment options • Attraction for delegates

authorisation, so in the pre-launch phase only non-promotional activities can be carried out. At this stage, programmes on disease awareness and exploring unmet medical needs can help define a new product's role.

Secondly, non-promotional events and materials can be used to attract delegates in a competitive market environment and demonstrate a broad corporate commitment to a therapy area or to healthcare provision in general. This can raise a company's profile, underpin corporate values and help build company brand value.

A non-promotional approach may also be useful when a company is entering a new therapy area, has a portfolio of products within a particular disease area or has a first-in-class agent with a new mode of action. Under these circumstances, it is still possible to present product data as part of a balanced educational programme (see Figure 2 above).

NON-PROMOTIONAL v ACCREDITED CME

During the last five years, there has been increasing availability and uptake of CME events across Europe. The preferred term in the UK is Continuing Professional

Development (CPD), which is broader and encompasses non-clinical as well as clinical skills training. This is also the preferred term of the European Union of Medical Specialists (UEMS) and is likely to gain wider use.

Increased awareness of CME in Europe has been borne out by our recent intra-company survey conducted across our European network, where all five major European markets reported high levels of awareness of CME and an increasing number of CME events. Interestingly, all markets also expected increased regulation of CME and were watching closely for any further changes to US guidelines. Another consistent finding was that all markets expected the development of similar initiatives for other healthcare professionals such as nurses and pharmacists.

CME events and enduring materials are formally accredited by independent national bodies, such as the Royal College of Physicians in the UK. Pan-European accreditation can also be obtained for educational meetings via the European Accreditation Council for CME (EACCME). Part of the UEMS, this body facilitates access to CME for European doctors, maintains quality standards and allows the

recognition and transfer of credit points.

In general, the process of CME accreditation for a meeting involves submitting the educational rationale (needs assessment), learning objectives, event agenda, faculty and details of sponsorship to the accrediting body for approval. Points are awarded, with some mutual recognition between different European countries and with the US. Attendees complete a self-assessment exercise and receive attendance certificates that can be used to support their own personal development plans.

The benefits to a pharma company in supporting accredited CME:

- These events are perceived as high quality and unbiased, as the content is driven by physicians who are experts in their field
- Product awareness can improve (within a balanced framework)
- The activities address clearly defined medical educational needs and contribute to the lifelong learning that underpins improved patient care
- Through CME activities, there can be discussion and awareness of advances in medicine.

The differing options of promotional, non-promotional medical education and accredited CME are appropriate in different situations and should be selected accordingly (Figure 2 above).

THE ROLE OF PHARMA IN ACCREDITED CME

Although the role of pharma companies in CME-accredited activities is very limited, the following actions need to be undertaken by any pharma company considering offering this form of support:

Our recent intra-company survey reported high levels of awareness of CME in all five major European markets

The activity supported by pharma companies and considered most important by doctors was non-promotional programmes

- To work with a reputable CME provider to ensure the programme is conducted within CME regulations – the proposal should include a needs assessment, have clearly defined learning objectives, contain an outline of the programme, and possibly indicate faculty
- To ensure the activity is aligned with corporate ethos and objectives
- To establish suitable internal processes to provide sponsorship
- To note that there can be restrictions on sponsor attendance at the event
- To review feedback, and action it appropriately.

And, of course, all the above actions occur within a complex regulatory environment and must conform to national and international laws, company operating policy and industry codes of practice. At present, input into accredited CME events from pharma companies varies from country to country in Europe but is expected to become limited to financial support only (as in the US) to maintain the impartiality of CME.

It is interesting to note that our recent survey of more than 400 medical opinion leaders showed that the provision and funding of educational activities was the second most important thing that doctors felt pharma could do more of (Ogilvy4D Clinical Expert Survey, 2007).

Moreover, the activity supported by pharma companies which was considered most important by doctors was also non-promotional – namely, the provision of educational programmes without any product bias to support patients.

The same survey showed that CME programmes and development of other educational materials were among the most common activities that opinion leaders were involved in with pharmaceutical companies.

Digital delivery channels, eg, e-learning, are likely to become the most frequently used and most cost-effective options in the future

CRITICAL SUCCESS FACTORS

Critical success factors for accredited CME activities fall into three broad areas:

- Expert faculty – well versed with current and future CME guidelines
- Experienced CME provider – to ensure CME guidelines are adhered to at all times, record attendance, facilitate the achievement of learning objectives, etc
- Insightful clients – those who understand CME and are prepared to play by the rules.

IS ACCREDITED CME THE RIGHT ACTIVITY?

To establish if accredited CME is a suitable option for you, ask yourself key questions such as, is there an educational need for the activity, do you trust the CME provider to deliver this CME programme within guidelines, is there sufficient time to gain accreditation (it takes six to eight weeks), does the activity include a self-assessment for participants, and, of course, is the activity aligned with regulations such as the ABPI Code and your individual company directives? If you answer “no” to any of these initial questions, you should reconsider your options.

WHAT THE FUTURE HOLDS

It seems likely that over the next five years the use of non-promotional medical education strategies will increase and pharma companies will raise their corporate profiles by supporting a broad range of training activities for doctors and other healthcare professionals. This is likely to be linked to an increased use of e-learning, with the possibility of novel and highly individualised personal development programmes.

Our understanding of adult learning has advanced in the last 20 years and access to digital technology has already opened up new delivery channels and new ways to learn. Whilst there has always been widespread agreement that CME/CPD is a valuable ethical commitment, it has been hard for healthcare professionals to set aside dedicated time for study.

E-learning allows the healthcare professional to manage his/her time more effectively and is a natural progression from current undergraduate teaching. Thus,

digital delivery channels are likely to become the most frequently used and the most cost-effective options in the future.

Digital formats include:

- Interactive CD ROMS
- Podcasts
- Webcasts and tutorials
- Radio and TV broadcasts
- Disease education websites
- Interactive treatment pathways
- DVDs
- e-books
- Text messaging
- Moderated discussion/chat rooms
- Blogs
- Virtual patient applications
- Digital case studies
- Online physician communities.

The EACCME is already developing a position on e-medicine, including e-learning, and it is likely that the organisation will provide pan-European accreditation of both meetings and enduring materials in the not-too-distant future, in line with the situation in the US. It is expected that accredited e-materials in Europe will need to comply with similar standards of accuracy, content, independence, quality, peer-review and certification as events do at present. This will give doctors increased flexibility to choose how, when and what they learn.

In the US, where CME is highly regulated, there is continued debate on the role of commercial companies. Whilst we cannot say that what happens in the US will automatically happen on this side of the Atlantic, it seems reasonable to assume that the accreditation rules will be interpreted more strictly.

So what will this mean for pharma marketing? Whilst there will still be an important role for the sales representative, there is likely to be a shift away from traditional AIDA-driven (ie, awareness, interest, desire, action), product-focused marketing to less overtly promotional approaches and a more balanced non-promotional approach. This refocusing will be welcomed by healthcare professionals and has the potential to improve patient care across Europe, as well as to provide benefits for the pharmaceutical industry.

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