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8 December 2011

Mr Richard Bergström
Director General, European Federation of Pharmaceutical Industries
Leopold Plaza Building, Rue du Trône 108
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An open letter from the Good CME Practice Group to UEMS and EFPIA

Dear Dr Borman and Mr Bergström

As the Good CME Practice (gCMEp) Group we are writing to the European Union of Medical Specialists (UEMS) and the European Federation of the Pharmaceutical Industry (EFPIA), following discussions during November at the Fourth European CME Forum meeting in Amsterdam and the UEMS meeting in Brussels, to call on you to help create a legally compliant framework for pharma-supported Continuing Medical Education (CME) in Europe.

The gCMEp Group came together as a collaborative partnership between European CME providers at the European CME Forum meeting in 2009. The 14 participating organisations are dedicated to the consistent implementation of high standards in the development of independent education within the European medical education sphere, specifically CME. Our aim is twofold:

1. To provide practical guidance to education providers for maintaining quality in their provision of CME, ensuring that the guidance complies with the framework of CME accreditation body guidance whilst also meeting the Codes of Conduct that govern the pharmaceutical company supporters.
2. To demonstrate to other CME stakeholders, namely CME accreditation bodies and pharmaceutical company supporters, that the providers who follow the gCMEp standards, are also fully compliant with the regulations of the CME accreditation bodies and EFPIA.

During the development of our own guidelines we concluded that successive guidelines and regulations from UEMS and EFPIA, and other self-regulatory or voluntary organisations, are failing to consider the very real practical needs of the providers and financial supporters. In our internal activities and discussions, it has become apparent that providers face particular challenges with reference to the interface between the pharmaceutical industry codes of conduct and the CME guidance provided by UEMS-EACCME and other European CME accreditation bodies. In some cases, we have found that the relevant codes and guidances are directly opposed to one another, creating a significant conflict for those attempting to deliver CME that meets all relevant requirements.

In our collective experience, in the absence of explicit guidance from either the pharmaceutical regulatory bodies, or the CME accreditation bodies, pharmaceutical companies often take the position that they are legally required to take formal steps to approve **all** content of CME meetings (e.g. programme, faculty selection, abstract book, course materials, slides, etc.) in accordance with their promotional code of practice – thus controlling content, also directly to contract with the faculty – thus controlling the Chair and speakers, and stipulating how the finances are spent – thus “restricting” the “grant”. In so doing, the company renders the event outside of the accreditation criteria, under the UEMS requirements that CME events are free from any attempt by the supporter to influence the programme or content. We are dismayed to note that many educational programmes following this level of pharma control are also eventually accredited.

One solution is to clarify the distinction between education and promotion. As education should not offer direct commercial benefit to the company, one way of distinguishing the two activities would be in funding CME by way of a formal “hands off” or “arms’ length” grant which specifically implies absence of commercial benefit. As far as we know, one regulatory authority in Europe that is prepared to make a statement to this effect is the Prescription Medicines Code of Practice Authority (PMCPA) in the UK. This authority has acknowledged the acceptability of “hands off” or “arm’s length” funding as being indicative of the absence of pharma control. Under these circumstances, the promotional code of conduct is explicitly stated not to be in effect, allowing pharmaceutical companies to be confident that they are not required to review and approve content. However, we are not aware of an instance where this guidance has been used in the UK CME (CPD) setting.

We understand that the use of this terminology and status is modelled on European tax regulations that offer VAT exemption for activities for which a company gives a grant, and for which it receives no direct commercial benefit: a basic requirement of CME. Under this banner, financial support is provided by the company in response to an external request from a provider and the company is thus able to step away from responsibility for the content, on the proviso that it does not interfere with, or take active part in, any aspect of the planning or delivery of the activity. The activity is deemed to be non-promotional in its essence. While this model seems a good fit for CME activities, currently EFPIA does not offer clear guidance for this kind of activity, and UEMS misses the opportunity to insist on seeing evidence of “hands off” or “arms’ length” grant funding. The new UEMS document on the Accreditation of Live Educational Events states that the provider must certify that “industry-based requirements” are met, and thus further compounds the problem.

Based on the apparent paradox between the various sources of guidance, we would like formally to request that EFPIA and UEMS initiate a dialogue that will facilitate resolution of this matter and create compatible, or better still, joint guidance for providers and pharma supporters alike. We believe that EFPIA must indicate to its members what level of involvement they should have in the CME programmes for which they provide grants, or at least clarify that CME programmes are deemed to be outside the scope of the promotional code, and UEMS should stipulate what level of scrutiny they believe the pharma supporters have the right to apply. Furthermore it would be useful if EFPIA – as representatives of the European Pharmaceutical Industry – and UEMS were in agreement as to exactly what pharmaceutical companies are required to do, and able to contribute, around the CME activities for which they provide grants.

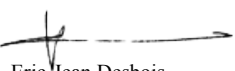
We therefore request that UEMS and EFPIA consider the following points and clarify the positions for the respective audiences in their guidelines and working practices:


1. That the CME accreditation requirements demands contractual evidence of the sources of funding and its independence, and that EFPIA regulations puts in place the facility to do this.
2. Systems are put in place so that CME accreditation can be used as evidence of “hands off” or “arms’ length” funding, clearly defining the educational aspect of this activity, and distinguishing it from promotion.
3. UEMS and EFPIA agree on a mutually acceptable structure for pharma commissioning or funding of CME activities in Europe, keeping commercial functions at arms’ length from direct involvement to eliminate inappropriate commercial influence.
4. That the guidance is clear, with punitive measures elaborated for cases of non-compliance.

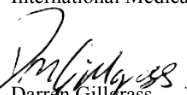
If these basic tenets are not met and educational programmes are not seen legally as being separate from the commercial promotional activities of the pharmaceutical industry, we fear that European CME may become increasingly dysfunctional, with both the pharmaceutical industry and the medical profession facing ever more intense public scrutiny.

Yours faithfully,

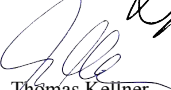
The Good CME Practice Group


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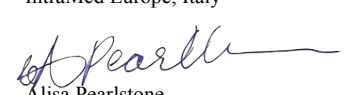

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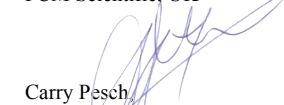

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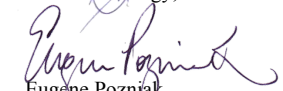

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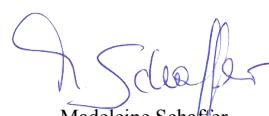

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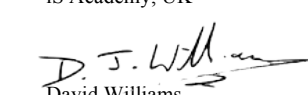

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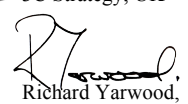

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