

*European CME in practice:
Update and case history*

MedComms Networking meeting

Prof. Robin Stevenson
Eugene Pozniak

January 2012

Today's agenda

- ❖ Why CME, why now?
- ❖ Evolving standards
- ❖ Case history (part 1)
- ❖ Working break - looking at UEMS-EACCME Guidelines
- ❖ Case history (part 2)

Eugene Pozniak - Hat 1

Siyemi Learning, Manchester, UK

Eugene's primary income comes from being Managing Director of **Siyemi Learning** (of which he is sole owner), an independent European CME Provider based in Manchester, UK.

He works on an individual project basis delivering CME accredited education, meetings or online, with or without collaborative education providers (e.g. European hospitals, European communications agencies, US accredited providers) and acts as a consultant to European regulatory bodies and the pharmaceutical industry.

Has worked exclusively in CME since 2000 – delivering over 500 hours of accredited live events and 50 hours of accredited e-learning.

Eugene writes regularly about CME. Articles can be found via www.siyemi.org

The logo for Siyemi Learning, featuring the word "siyemi" in a blue, lowercase, serif font. The letter 'i' has a distinctive dot that curves upwards and to the right.

Eugene Pozniak - Hat 2

Programme Director, European CME Forum

Eugene is joint founder and guarantor (with Peter Llewellyn) of **European CME Forum** – a Not-For-Profit organisation, bringing together CME professionals, regulators and supporters active in European CME.



European CME Forum was set up in 2007 as an independent platform for dialogue between interested parties in European CME.

Record of all activities are freely available for download at www.europeanCMEforum.eu

Good CME Practice Group – 2009

www.gCMEp.eu



Journal of European CME – JECME

Editor-in-Chief: Prof. Robin Stevenson

Peer review, Open Access – target time to publication 10–12 weeks

Publisher: Informa

Call for manuscripts June 2011 – Full launch next month

www.jecme.eu

Journal of
European CME

The Open-Access Journal on CME-CPD Practice

Learning objectives - my guess

- ❖ After today's session you will be able to:
 - ❖ Describe the current CME-CPD environment in Europe
 - ❖ Understand the role of the pharma supporter
 - ❖ Cite the key factors that define a CME programme

Why CME, why now?

Overview

1999-2005

Birth and early years

2005-2010

Development

2010-now

Confusion

Birth of modern CME 1999-2005

❖ **CME bodies/HCP**

❖ **Providers**

❖ **Industry**

❖ **Setting rules**

❖ **No role**

❖ **Extended
relationships**

“Development” 2005-2010

❖ **CME bodies/HCP**

❖ **Providers**

❖ **Industry**

❖ **Assertive**

❖ **Free for all**

❖ **Extended
relationships
further**

2010/2011?

- ❖ Transparency and accountability
 - ❖ Bribery Act
 - ❖ Foreign Corrupt Practices Act
 - ❖ Sunshine Act
 - ❖ GPP2
 - ❖ New promotional Codes of Practice
 - ❖ HMRC

“Confusion” 2010-present

❖ **CME bodies/HCP**

❖ **Providers**

❖ **Industry**

❖ **Confused?**

❖ **Want / need to
be more
professional**

❖ **Want / need to be
more responsible,
but don't know
where to find
guidance!**

Why CME, why now?

The players

CME Providers in Europe

CME Providers in Europe

- ❖ Academic
 - ❖ Medical Societies / Associations
 - ❖ Local employer / hospital
- ❖ Commercial

“Pure promotion”

Press Ad

Detail Aid

Market access

Mailing Campaign

Professional Relations

Public Relations

Paid-for journal

Ad Board (2)

Sponsored Supplement

Stand Alone Meeting

e-learning (2)

Satellite Symposium

Publication Planning

Ad Board (1)

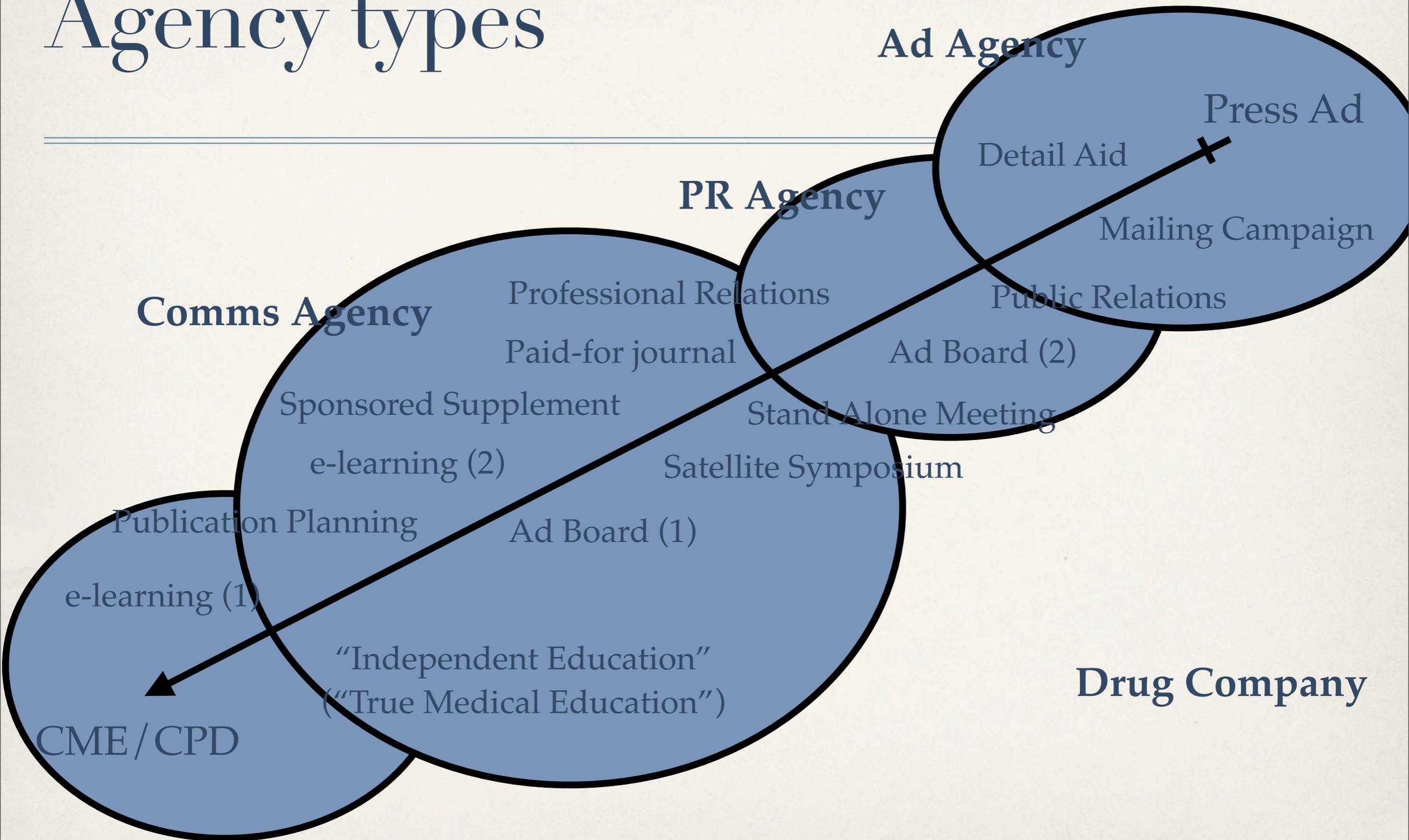
e-learning (1)

“Independent Education”
 (“True Medical Education”)

CME/CPD

“Pure education”

Agency types



A full explanation can be found here: <http://www.inpharm.com/news/155113/cme-spotlight-education-providers-pharma-guidance>

Promotion | Education

Prof Robin Stevenson

Member EACCME Taskforce
Editor JECME

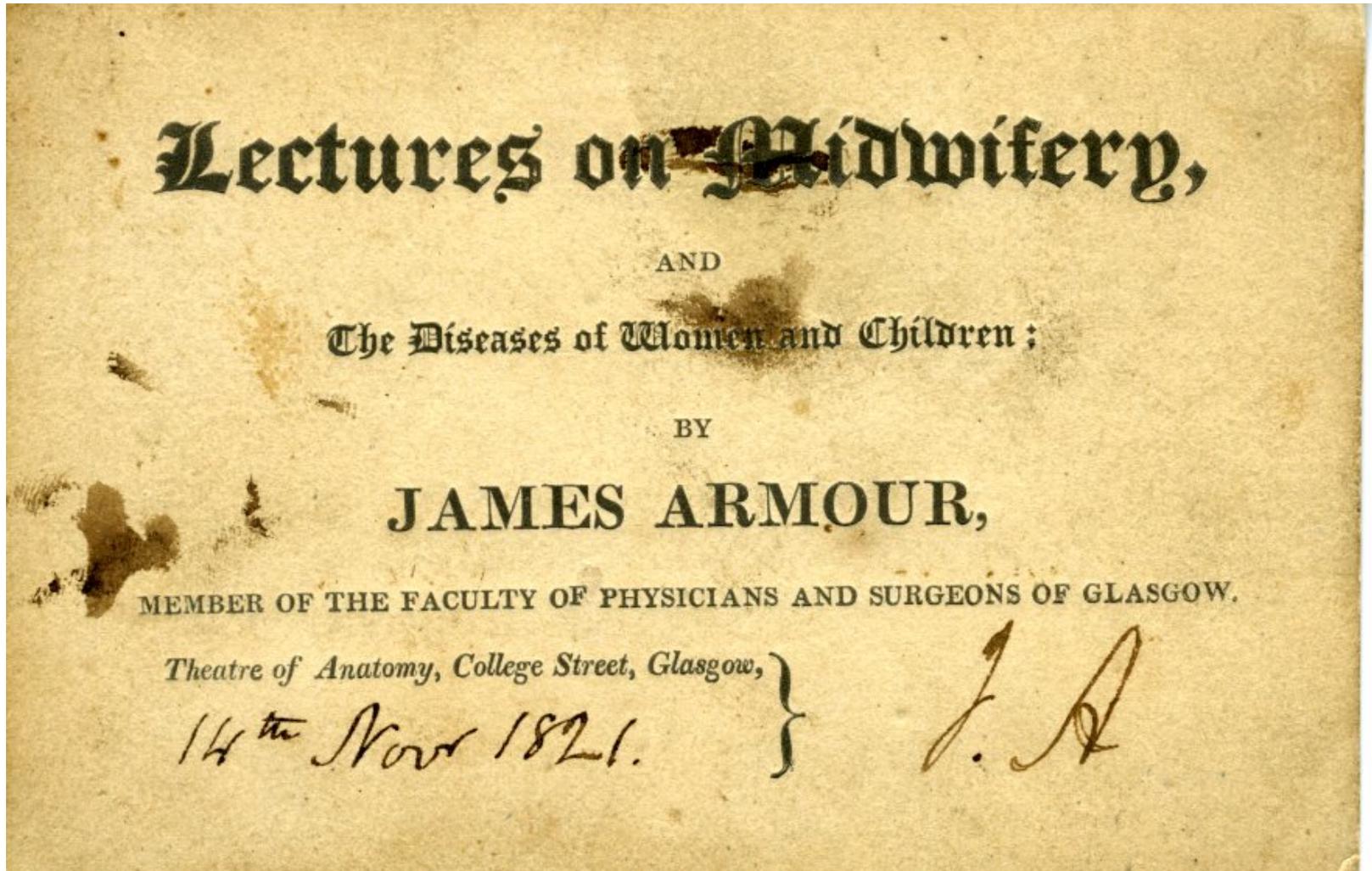
Evolving Standards in European CME

Before CME

Fifty years ago:

- Limited European travel
- Local/national meetings – different languages
- Journals
- Books
- Lectures

Traditional Lecture



Lecture theatre



Beginnings of CME

- 1968: AMA Physician's Recognition Award (PRA)
- 150 hours CME over 3 years
- Europe – National Regulatory Authorities
 - UK General Medical Council
 - Royal Colleges of Medicine
- Regulation – quality control

ACCREDITATION

1981 - Accreditation Council for Continuing Medical Education ACCME (USA)

- Provider Accreditation
- Regional/State CME
 - a. State medical societies accredited by ACCME
 - b. Providers accredited by state medical societies
- National CME
 - Providers directly accredited by ACCME

Development of European CME

Past two decades:

- International meetings – English language
- e-learning
- Journals
 - International/European
- **Accreditation**
- European in addition to National accreditation



UNION EUROPÉENNE DES MÉDECINS SPÉCIALISTES
EUROPEAN UNION OF MEDICAL SPECIALISTS



Union Européenne Des Médecins Spécialistes (UEMS)

- UEMS (European Union of Medical Specialists) founded in 1958
- Managed by Council composed of Delegates from National Regulatory Authorities
- Contains Sections & Boards representing most recognised specialties from each country

European CME

- European Accreditation Council for CME (EACCME): established by UEMS in 1999, based on the US model of ACCME
- Accreditation limited to European and international events
- EU principle of subsidiarity
 - Dual accreditation
 - a) National Accreditation Authorities (NAAs)
 - b) EACCME

Operation of European system Event Accreditation

- Provider sends programme of planned event to EACCME
- EACCME requests event assessment from:-
 - UEMS specialty sections/ESABs
 - NAA of host country
- Double assessment (subsidiarity)
- EACCME awards creditable value to provider
- Provider awards credits to participants.

European Specialty Accreditation Boards (ESABs)

Joint boards composed of members from UEMS
Sections and European Scientific Societies

Cardiology (ESC)	EBAC
Pneumology (ERS)	EBAP
Infectious Diseases (ESCMID)	EBAID
Urology (EAU)	EU-ACME
<i>Oncology (ECCO)</i>	<i>ACOE*</i>
<i>Haematology (EHA)</i>	<i>ECAH*</i>

**No Specialty Section in UEMS*

Continuing Medical Education – CME AIMS

- Direct to gaps where a need for the education is assumed.
- Deliver in a way that stimulates the learner to think critically and to relate learning to clinical practice.
- Test and stimulate learning during the educational process by interactive participation.
- Avoid bias by commercial, editorial, social or political influence.

Reasons for Under-performance

- Conflict between the interests of the provider and the learner which results in bias.
- CME directed disproportionately towards specialties that use drugs or devices.
- Needs assessment may relate more to the needs of the drug and device industry than to the doctors.
- Lack of appreciation of educational technology resulting in flat, didactic delivery with no element of learner participation.

Davis, JAMA 1995;274:700-705

- Widely used CME delivery methods such as conferences have little direct impact on improving professional practice.
- More effective methods such as systematic practice-based interventions and outreach visits are seldom used by CME providers.

Davis, JAMA 1999;282:867-874

- Interactive CME sessions that enhance participant activity and provide the opportunity to practise skills can effect change in professional practice and, on occasion, health care outcomes.
- Based on a small number of well-conducted trials, didactic sessions do not appear to be effective in changing physician performance.

Cochrane review 2007

- Interactive workshops can result in moderately large changes in professional practice
- Didactic sessions alone are unlikely to change professional practice.

Johns Hopkins Report 2007

- Print media less effective than live media
- Multimedia more effective than single media
- Interactive techniques more effective than non-interactive techniques
- Multiple exposures to CME activity more effective than a single exposure

MACY Report, Nov. 2007

- Traditional lecture-based CE has proven to be largely ineffective in changing health professional performance and in improving patient care.
- Practice-based learning and improvement is a promising CE approach for improving the quality of patient care.
- Interactive scenarios and simulations are promising approaches to CE, particularly for skills development,
- Current accreditation mechanisms for CE are unnecessarily complex yet insufficiently rigorous.

Lecture

Lectures on Midwifery,

AND

The Diseases of Women and Children;

JAMES ARMOUR,

MEMBER OF THE FACULTY OF PHYSICIANS AND SURGEONS OF GLASGOW.

Professor of Anatomy, College Street, Glasgow,

14th Nov 1821.

J. A.

D 9908

1. Objectives of the CME activity
 - Learning objectives
 - Target participants
2. Programme
3. Provider
 - Personal data / Qualifications
 - Structure and organisation of the provider
 - Previous experience
 - Potential conflict of interest
 - Individual responsibility of providers
4. Commercial interest
5. Quality assurance
 - Non-biased education
 - Attendance
 - Report
 - Feed back
 - Assessment

Not included in D 9908

- Needs assessment
- Type of educational delivery
 - didactic/interactive
- Outcome assessment
 - effect on clinical practice/patient benefit

EACCME taskforce

- Criteria for e-learning 2008
- Criteria for Live Events (LEE) 2011

Types of Accreditation

- **Event/activity accreditation (AA)**
 - European countries except Austria, France and Italy
 - Hospital doctors – international events in Europe
 - Family doctors in USA and Canada
- **Provider accreditation (PA)**
 - Hospital doctors in USA and Canada
- **Performance improvement (PI)**
 - USA

Logistics - AA

- Every activity submitted to regulatory agency
- EACCME sends applications to Specialty Sections, about 40, or to European Specialty Accreditation Boards (ESABs)
- Each reviewed by up to 3 doctors, usually consultants (content-specific)
- EACCME sends applications to NAA of host country
 - dual accreditation
 - EU subsidiarity
- Decision based on review of programme and speakers

Logistics - PA

- Providers submit details of recent activities
- ACCME volunteer reviewers assess submission in relation to 22 criteria published by ACCME (not content-specific)
- Accreditation awarded:
 - Provisional/initial for 2 years
 - Standard for 4 years
 - With commendation for 6 years
- Cost of accreditation - US\$7500
 - US\$3500 annually to maintain accreditation

Logistic comparison

- AA more resource-intensive than PA – every specialty must recruit reviewers
 - EACCME pays e-learning reviewers
- Strict criteria in PA may reduce numbers of providers – increased efficiency
- In AA number of activities increases inexorably
 - workload proportional to number of activities
- Economy of scale favours PA

CME Quality - PA

- In USA, 50% of providers non-compliant with some aspect of the 22 criteria. Virtually 90% demonstrate compliance at a one-year review.
- Previous accreditation of Medical Education and Communication Companies (MECCs) lead to commercial bias .
- Updated Criteria (2006) and Standards for Commercial Support (2004) have reduced MECC accreditation.
 - possibly too stringent now
- Slow to deal with bad providers

CME Quality - AA

- More than 95% of applications for accreditation are successful
- European meetings still dominated by didactic lectures with token periods of discussion
- Participant feedback and post-conference reports seldom affect provider performance
- Commercial bias can be detected
- Difficult to assess quality from looking at the programme and speakers

Evolution of standards

- Providers
 - Didactic to interactive
 - Large to small groups
 - ?Performance improvement
- Regulators
 - Quality assurance
 - Event/activity to provider accreditation

CME Accreditation bodies in Europe

- ❖ European Accreditation Council for CME (UEMS-EACCME)
- ❖ European Specialty Accreditation Boards (ESAB)
- ❖ National Accreditation Authorities (NAA)

EACCME

- ❖ Part of European Union of Medical Specialists (UEMS)
- ❖ Specialty boards and sections

ESABs

- ❖ European Board for Accreditation in Cardiology (EBAC)
- ❖ Accreditation Council of Oncology in Europe (ACOE)
- ❖ European Society of Medical Oncology (ESMO-MORA)
- ❖ European Board for Accreditation in Pneumology (EBAP)
- ❖ European Urology - Accredited CME (EU*ACME)
- ❖ European Board for Accreditation in Rheumatology (EBOR)
- ❖ European Hematology Association (EHA-CME)
- ❖ EBAID, EBACM, EACIC, etc. etc.

National Accreditation Authorities

- ❖ UK: >20 Royal Colleges and Faculties
- ❖ Germany: 16 State and the Federal authority
- ❖ Spain: 4 systems
- ❖ Italy: Central and regional control - and new provider accreditation
- ❖ France: watchful waiting

Evolving standards

The “rules” to follow

CME rules to follow

- ❖ CME bodies - UEMS-EACCME a rallying point, but all are at risk of becoming out of date with recent developments
- ❖ Industry - mostly nothing in CME, but...!
- ❖ Providers - now need their own rules

The “rules” to follow from gCMEp



Objectives

- ❖ To establish Core Principles as a standard and encourage uptake amongst all stakeholders to
 - ❖ improve quality of CME programmes in Europe
 - ❖ support all parties and users striving to improve programmes
- ❖ 4 Core Principles developed and submitted to consultation
 - ❖ Appropriate education
 - ❖ Balance
 - ❖ Transparency
 - ❖ Effectiveness

Principle 1

Appropriate Education

- ❖ CME providers should ensure that educational activities have clear learning objectives that are derived from a coherent and objective process that has identified performance gaps and unmet educational needs.
- ❖ The education must be designed to positively reinforce existing good practice and effect a sustained change in daily clinical practice as appropriate
- ❖ CME Checklist:
 - ❖ Needs assessment: identification of performance gaps and unmet educational needs
 - ❖ Clear demonstrable learning objectives identified
 - ❖ Content designed to effect sustained change in clinical practice

Principle 2

Balance

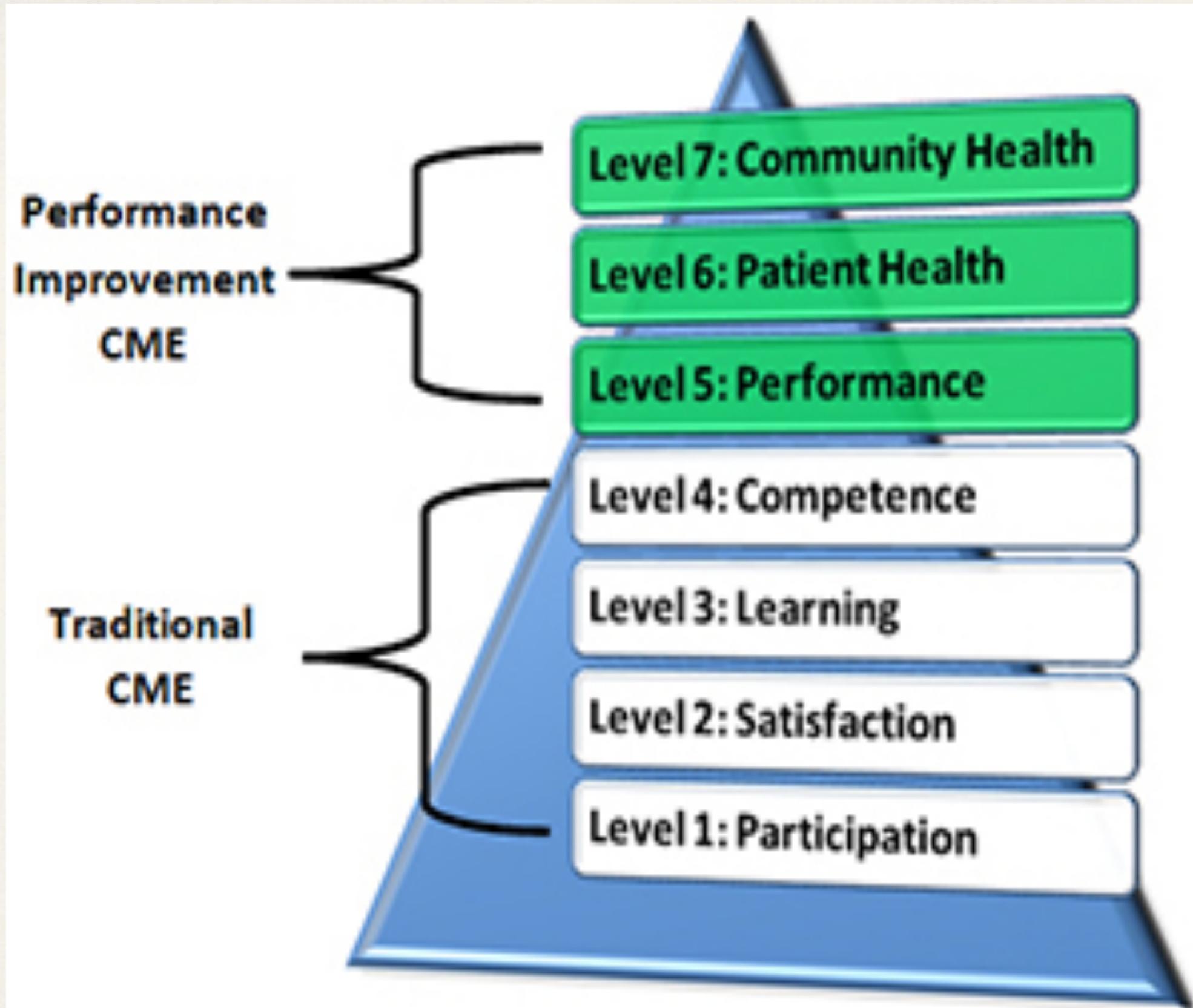
- ❖ Balance needs to be evident in content, faculty and review.
- ❖ Content has to be developed independently of the sponsor and reflect the full clinical picture within the framework of the learning objectives
- ❖ CME Checklist:
 - ❖ Content is fair, unbiased and related to current standards of care
 - ❖ Faculty is impartial and balanced
 - ❖ Mechanisms to encourage learners to feedback to content providers and accrediting bodies

Principle 3

Transparency

- ❖ All relevant information should be disclosed to the learner so that they understand fully how the content has been developed and presented.
- ❖ This includes the terms of the financial support, relevant disclosures of faculty and organisations involved in the development of the scientific content and the presentation of the programme
- ❖ CME Checklist
 - ❖ Learner should understand how everything has been developed and presented.
 - ❖ Disclose ... objectives, sources of funding, interests / CoI, people involved, structures, procedures, collaborators, external companies, writers, ... everything.

Principle 4



*Moore DE Jr, Green JS, Gallis HA. Achieving desired results and improved outcomes: integrating planning and assessment throughout learning activities.

J Contin Educ Health Prof. 2009 Winter;29(1):1-15.

Principle 4

Effectiveness

- Post-activity evaluation should measure satisfaction, knowledge uptake and intent to maintain or change behaviour in line with learning objectives
- CME Checklist
 - ❖ Testing to reflect defined performance gaps, unmet educational needs and learning objectives
 - ❖ Effectiveness can be measured against “Level 3 - Knowledge Gain” of the Moore scale:
 - ❖ Satisfaction, knowledge and / or skills gain, actual / intent to maintain or change behaviour,
 - ❖ Collect feedback that helps plan future activities

Case study

Case study

- ❖ **This is a fictional case, made up of scenarios all previously experienced by education providers in Europe. Please review the information and identify examples of good practice, and those that are bad. Also identify what, if anything, is missing.**
- ❖ **Use the guidance from the Good CME Practice Group, if needed, the additional standards to use for the purposes of this exercise are of the EACCME and EFPIA.**
- ❖ **At all times please remember that you are a European CME professional working with funding from a European pharma company, addressing the needs of a European target audience.**

New expectations in CME



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UEMS 2011 / 30

The Accreditation of Live Educational Events by the EACCME®

Adopted by the UEMS Council on 7th October 2011

Introduction

1) The European Union of Medical Specialists (UEMS) was founded in 1958 with the aim of representing the interests of specialist doctors at an international level. The UEMS is a non-governmental voluntary organisation comprising the national medical organisations that represent medical specialists in the European Union and in associated countries. With a current membership of 35 countries, and 39 specialist sections, the UEMS provides for the representation of approximately 1.4 million medical specialists working in Europe. The UEMS is committed to the promotion of the highest attainable quality of medical care for European citizens, the highest standards of medical education for doctors, and the free movement of medical specialists throughout Europe.

4) The UEMS acknowledges the need for CME credits as a simple means of confirming involvement in CME/CPD, hence has introduced a common “CME currency”: the European CME Credit (ECMEC). While the EACCME® provides a credit-based accreditation system, the UEMS draws attention to its policy, stated in the Basel declaration, that doctors should employ a range of educational methods and not rely solely on formally accredited CME for their continuing education.

5) The UEMS has agreements based on the mutual recognition of credit points with the American Medical Association – for live educational events and for e-learning materials – and with the Royal College of Physicians and Surgeons of Canada – for live educational events only.

Educational Objectives and Fulfilment of Learning Needs

11) The Provider must structure the LEE to fulfil defined educational needs.

The application must demonstrate that a “needs assessment” process has been completed, how that process was performed, and how relevant educational needs have been derived from that process.

(Essential criterion)

12) The Provider must define the “target audience” for whom the LEE is most likely to be suitable.

This must be explained in terms of the speciality/ies and seniority of doctor(s) most likely to benefit (henceforth referred to as the “Learner(s)”).

(Essential criterion)

13) The Provider must identify and communicate the expected educational outcome(s) of the LEE.

These must be explained in terms of the expected educational impact in knowledge, skills, attitudes or behaviours, or ethical lessons, and whether these are likely to have benefit in clinical practice or in broader professional areas.

(Essential criterion)

16) *The LEE must include methods to promote active learning.*

The application should state how this will be achieved. Examples include: multimedia presentations; protected question and answer sessions; opportunities for audience participation; key-pad votes and discussion; etc.

(Essential criterion)

18) The Provider must indicate the mechanism(s) by which it will be verified that the Learner has engaged with the LEE in order to fulfil the educational objective(s).

As a minimum this must involve a mechanism for confirmation of attendance at the LEE. The UEMS encourages the use of more sophisticated methods, such as smart cards confirming attendance at specific sessions, requiring the Learner(s) to complete questions based on the LEE material, requiring the Learner(s) to complete feedback forms, etc.

(Essential criterion)

20) The Provider must provide a short description of the Provider organisation(s).

The Provider must submit a short description of their own organisation, and any other(s) with which they are working with regard to this specific LEE, specifying, in each case, the organisation's contribution to the LEE. Where the Provider is a CME company producing a programme on behalf of another organisation (e.g. pharmaceutical or device manufacturer) their relationship must be fully disclosed.

(Essential criterion)

21) The Provider must provide a summary of other educational activities for which it has been responsible in the preceding two years.

This information must be provided whether or not these educational activities were submitted to the EACCME® for accreditation. (See also paragraph 40)

(Essential criterion)

22) The Provider must state the names and job titles of the individual(s) responsible for preparing the LEE.

The name and contact address of the person/organisation primarily responsible for the delivery of the LEE must be provided. In addition, if these are from different organisations, the names and contact addresses must be provided of the persons/organisations responsible for the planning of the LEE, the administration of the LEE, the scientific programme content of the LEE, and for billing purposes.

(Essential criterion)

23) The Provider must provide the name, title and contact details of a medical practitioner who will take responsibility for the application for accreditation of the LEE. This doctor must be registered with a Medical Regulatory Authority, and his/her registration details must be provided.

25) The Provider must ensure that all members of the Scientific and/or Organising Committee provide written declarations of potential or actual conflicts of interest.

All declarations of potential or actual conflicts of interest, whether due to a financial or other relationship, must be provided to the EACCME® upon submission of the application. Declarations also must be made readily available, either in printed form, with the programme of the LEE, or on the website of the organiser of the LEE. Declarations must include any fee, honorarium or arrangement for re-imbursment of expenses in relation to the LEE.

(Essential criterion)

26) The Provider must confirm that any actual conflicts of interest have been addressed.

Where there is an actual conflict of interest involving a member of the Scientific and/or Organising Committee, the EACCME® must be informed of how this has been addressed. The EACCME® considers it a responsibility of the head of the Scientific and/or Organising Committee to ensure that actual conflicts of interest are addressed.
(Essential criterion)

26) The Provider must confirm that any actual conflicts of interest have been addressed.

Where there is an actual conflict of interest involving a member of the Scientific and/or Organising Committee, the EACCME® must be informed of how this has been addressed. The EACCME® considers it a responsibility of the head of the Scientific and/or Organising Committee to ensure that actual conflicts of interest are addressed.
(Essential criterion)

27) In the context of addressing conflict of interest the Scientific and/or Organising Committee must ensure that the LEE will provide a programme that presents a scientifically balanced perspective of the subjects included.

This must include impartiality in the scheduling of subjects, lecturers and opportunity for discussion. Challenge through peer-review by participants during discussion sessions within the LEE can provide an effective safeguard.
(Essential criterion)

32) The source(s) of all funding for the LEE must be declared, and be made available to Learners in a readily available manner.

Failure by a Provider to disclose the means of funding of a LEE will lead to rejection of its application. The Provider must be able to provide, on request by the EACCME[®], documentation confirming the basis of the funding for the LEE.

(Essential criterion)

19) The LEE must be conducted in compliance with all relevant ethical, medico-legal, regulatory, industry-based and legal requirements.

For example, this should include: confirmation of confidentiality for patients and other participants, or consent to inclusion of non-identifiable details within LEE presentations, compliance with research ethics requirements, compliance with data-protection legislation, and copyright arrangements. It is essential to ensure that patients are not, and cannot be identified in any of the materials presented. The relevant legal, regulatory and industry-based standards will be those for the country in which the LEE is being held.

(Essential criterion)

33) All funding must be provided free of any attempt to influence the programme, individual sessions, subjects for discussion, content or choice of Faculty members.

The Scientific and/or Organising Committee must confirm that it has determined the content of all aspects of the LEE to be free of any attempt by sponsors to influence the Committee's decisions. The EACCME® will not support for accreditation LEEs that have been directly funded by, and/or will be provided by, the pharmaceutical and/or medical equipment industries.

(Essential criterion)

37) *All educational material must be free from any commercial bias (see appendix 5).*

Where there is a valid evidence base for a specific therapy or agent, this may be stated, but this must be referenced in a manner that is appropriate for a scientific journal.

(Essential criterion)

39) The EACCME® reserves the right to request doctors, who will be attending the LEE, to provide independent reports on the fulfilment of the criteria set out in this policy.

40) *The Provider's evaluation record for previous LEEs must be satisfactory. Should the Provider have had unsatisfactory ratings the Provider must be able to demonstrate that these have been addressed.*

The EACCME® will permit a Provider reasonable opportunity to comment on perceived inaccuracy of feedback, but also will expect Providers to demonstrate a commitment to address reasonable suggestions for improvement.

(Essential criterion)

Some final thoughts and questions

Good practice

- ❖ Pharma hands off
 - ❖ e.g. gCMEp, US rules,
 - ❖ Arm's length under EFPIA
- ❖ Faculty in control - no contracts- disclosures
- ❖ CME compliance, but currently...
 - ❖ poorly enforced

Bad practice - common pitfalls

- ❖ Pharma poor understanding: use of promotional codes
- ❖ Providers don't know what they are doing
- ❖ Doctors unaware of seismic changes

An example

- ❖ Lupus Academy (www.lupus-academy.org)
- ❖ Hands off (GSK rules - EFPIA rules - CME - HMRC)
- ❖ Consortium - European CME Forum lead
- ❖ Faculty completely in control

Ongoing developments

- ❖ Pharma CME understanding: e.g. I-PACME, EFPIA
- ❖ Clarification for providers: gCMEp group
- ❖ Closer collaboration of CME accreditation bodies

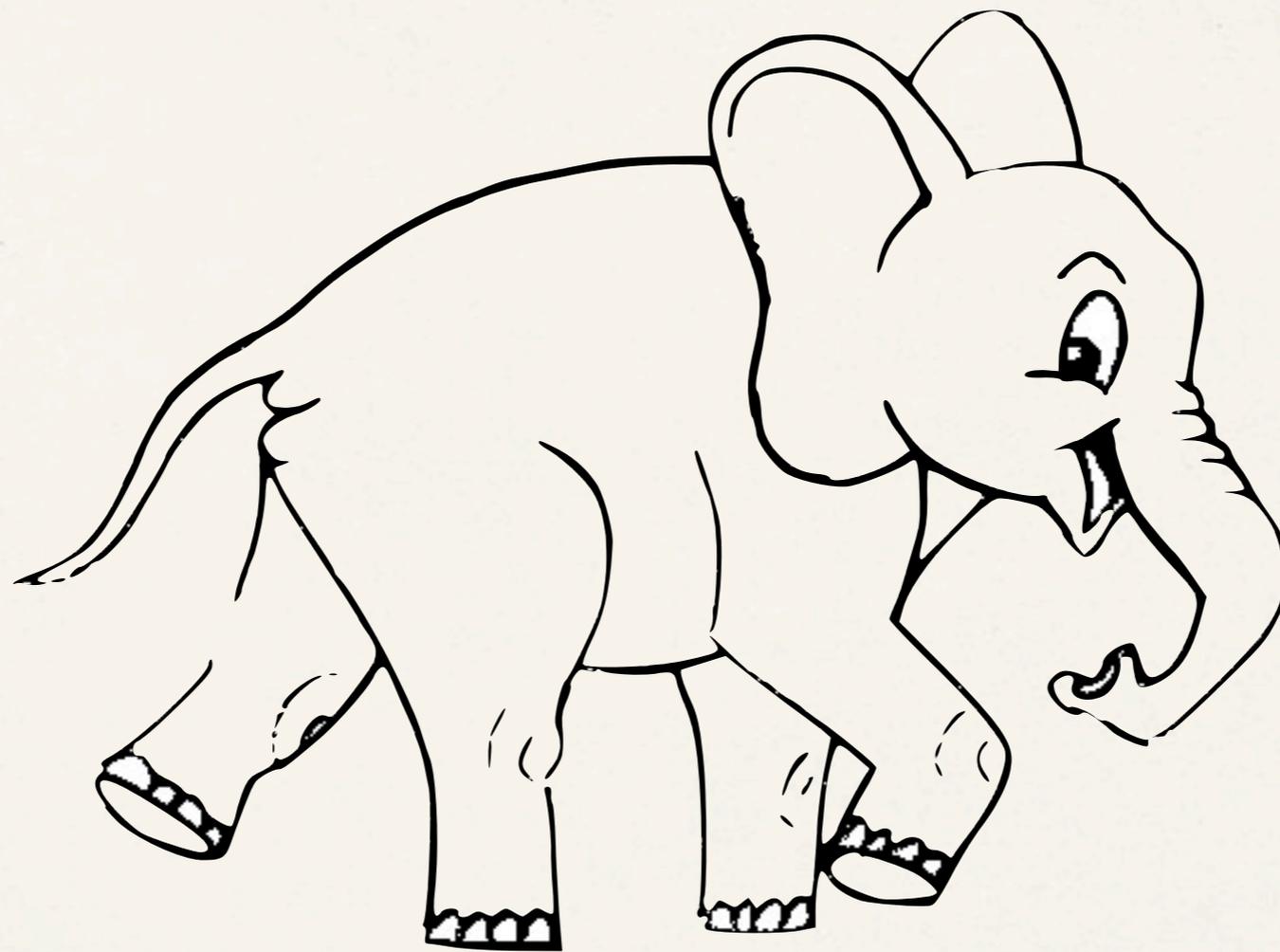
Future influencers

- ❖ Medical societies
- ❖ Patients
- ❖ Providers
- ❖ Press?

e.g. Ben Goldacre

- ❖ Trial by press
- ❖ www.guardian.co.uk/profile/bengoldacre
- ❖ www.badscience.net





❖ Government

Common goal

- ❖ To improve patient care

Learning objectives

- ❖ I hope that we have made a start to address these!
- ❖ After this session you will be able to:
 - ❖ Describe the current CME-CPD environment in Europe
 - ❖ Understand the role of the pharma supporter
 - ❖ Cite the key factors that define a CME programme
 - ❖ Others?

Thank you.



- ❖ #5ECF, London, 14-16 November 2012
- ❖ www.europeanCMEforum.eu