CME in Europe: latest guidelines and their practical implications for 2013

Eugene Pozniak

6 December 2012

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Siyemi Learning | European CME Forum – Manchester

Managing Director of **Siyemi Learning**, an independent European CME Provider based in Manchester, UK.

Worked exclusively in CME since 2000 – delivering over 500 hours of accredited live events and 50 hours of accredited e-learning, and a few credits of print CME.

Mainly Europe, also US, Latin America, Middle East, India, Japan.

Programme Director and joint guarantor (with Peter Llewellyn) of **European CME Forum** (2007) – a Not-For-Profit organisation, bringing together CME professionals, regulators and supporters active in European CME.

Editorial Board – **Journal of European CME (JECME)**

Founding member – **Good CME Practice Group (gCMEp)**

Executive Board – Global Alliance for CME (GAME)

What is CME about?

Cooperation, collaboration, talking with “the other side”

Agenda

CME in Europe: latest guidelines and their practical implications for 2013

- 1. Who does CME in Europe - who needs the Guidelines?
- 2. Why the need for Guidelines?
- 3. Practical implications

1. Who does CME?

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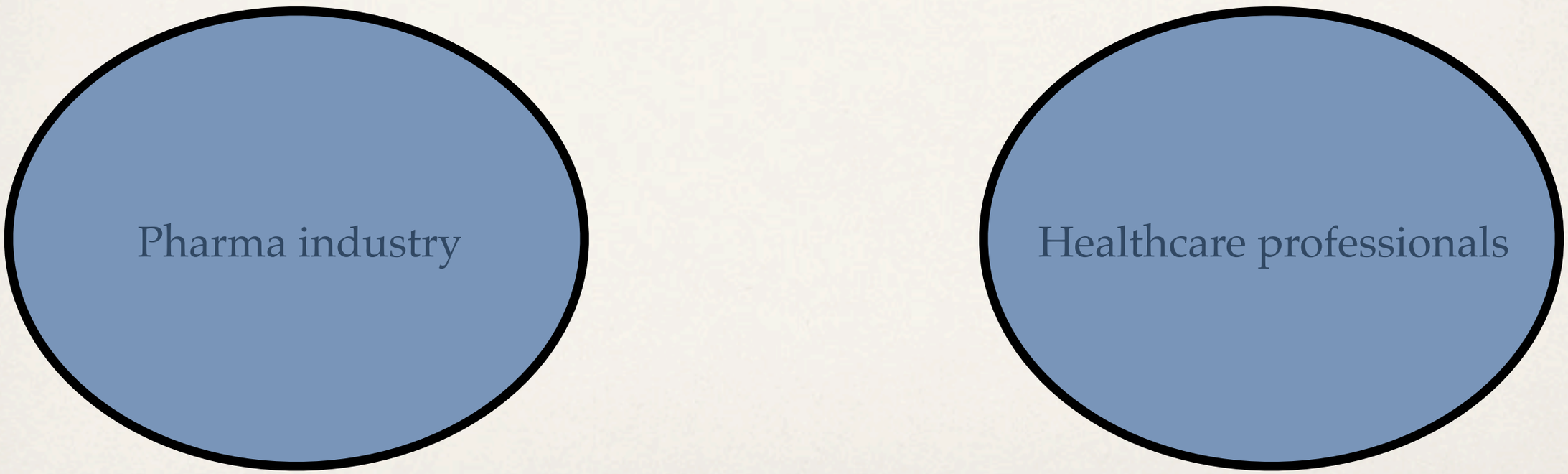

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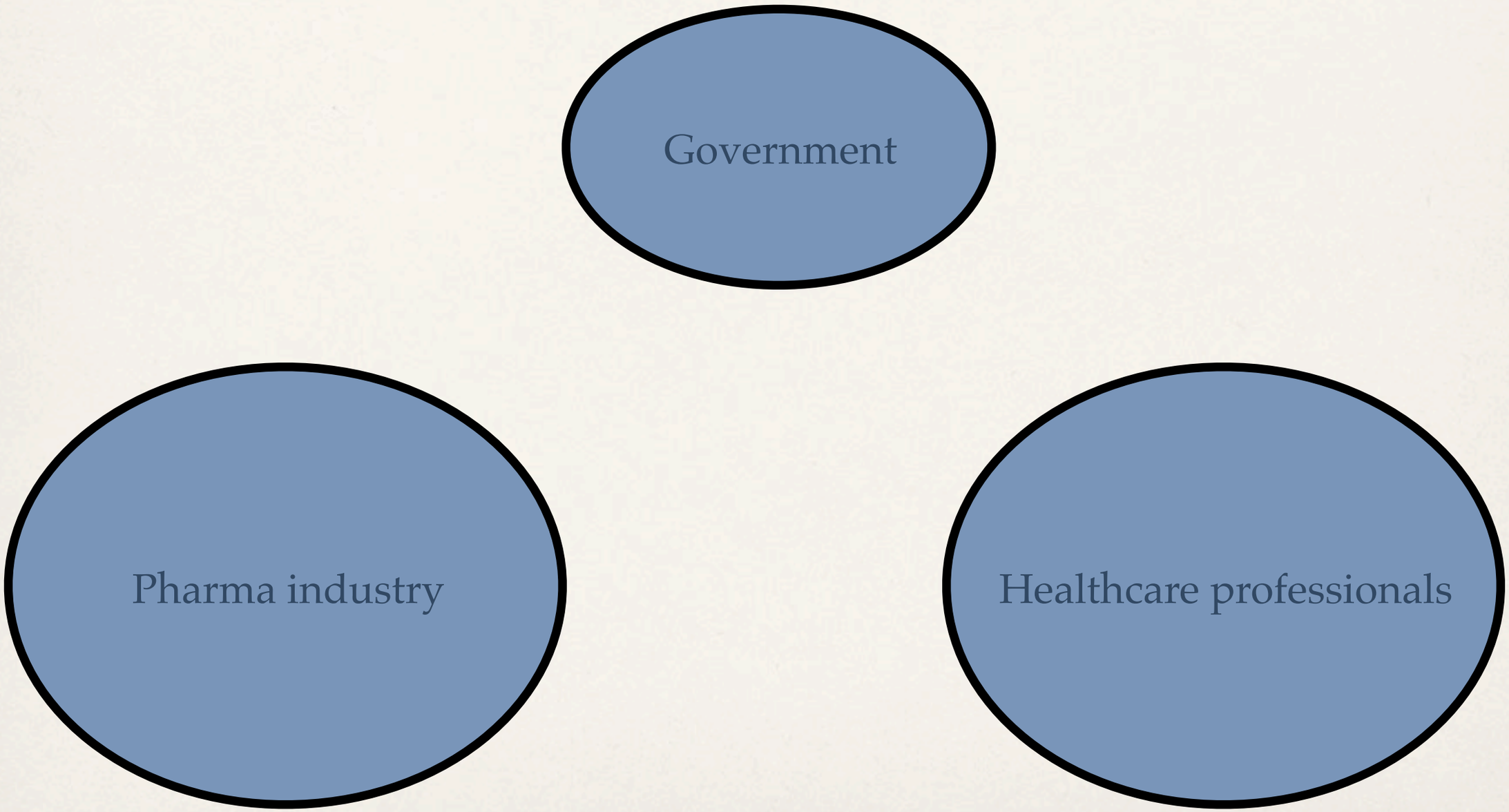

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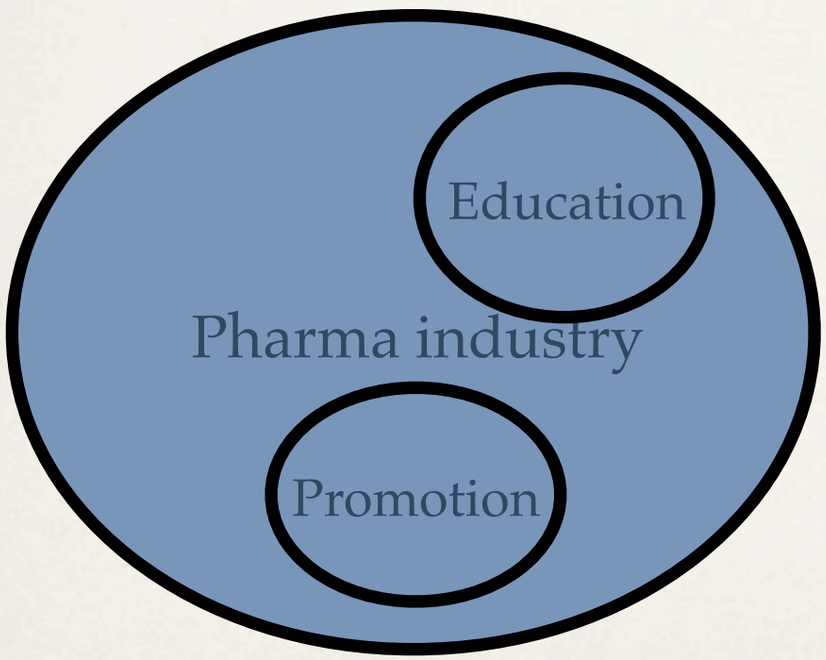

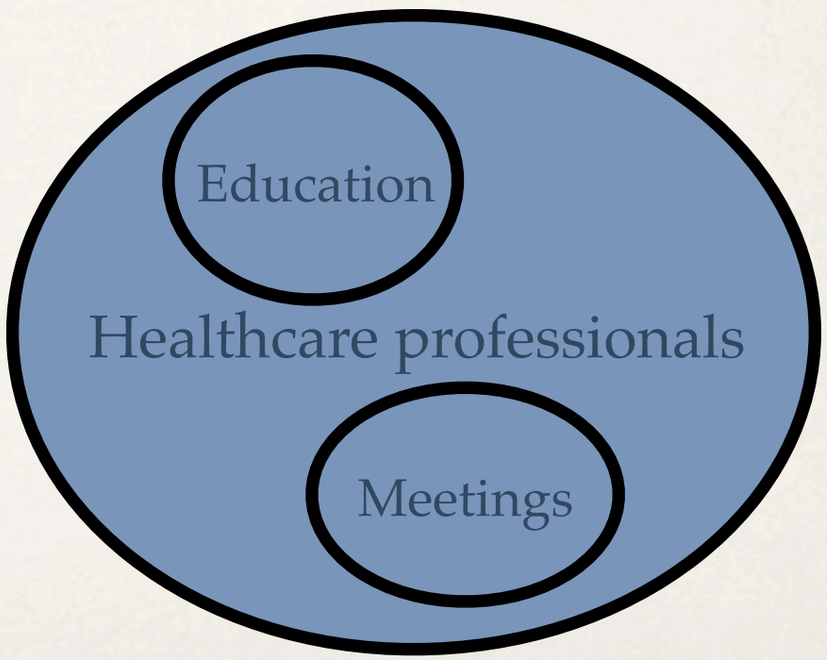

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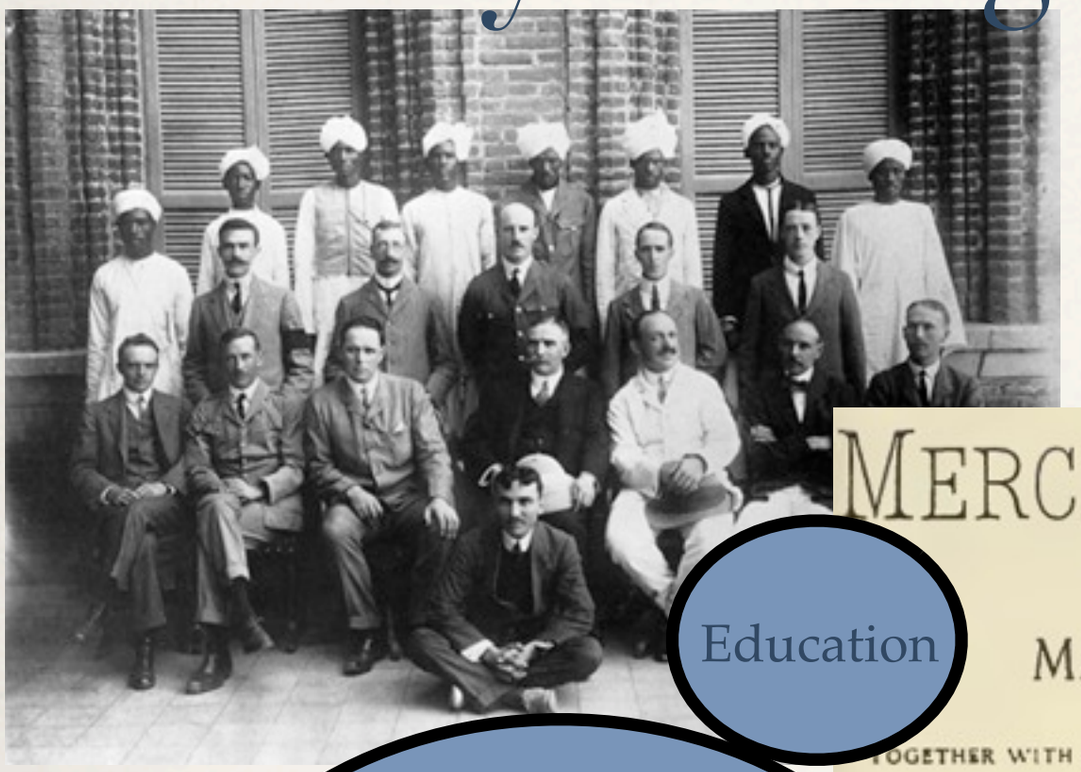
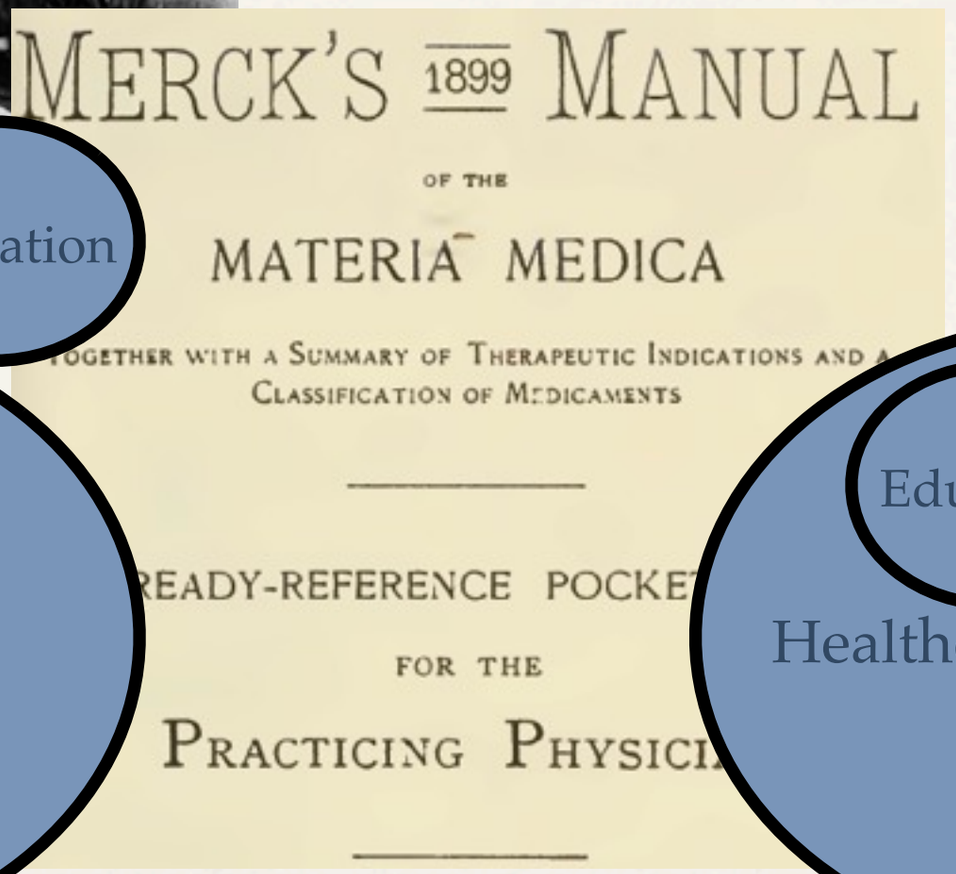
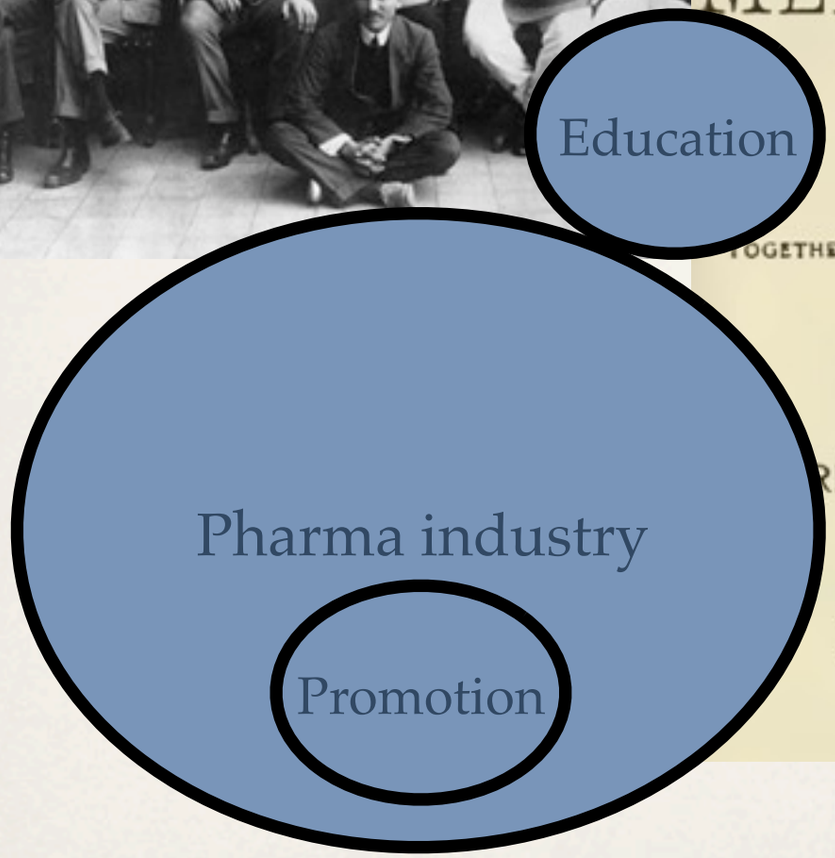
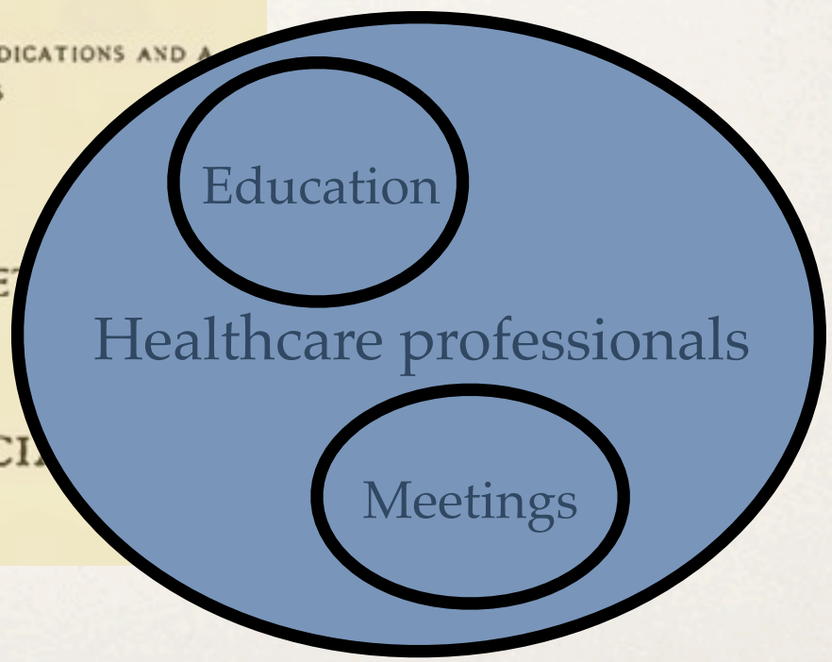
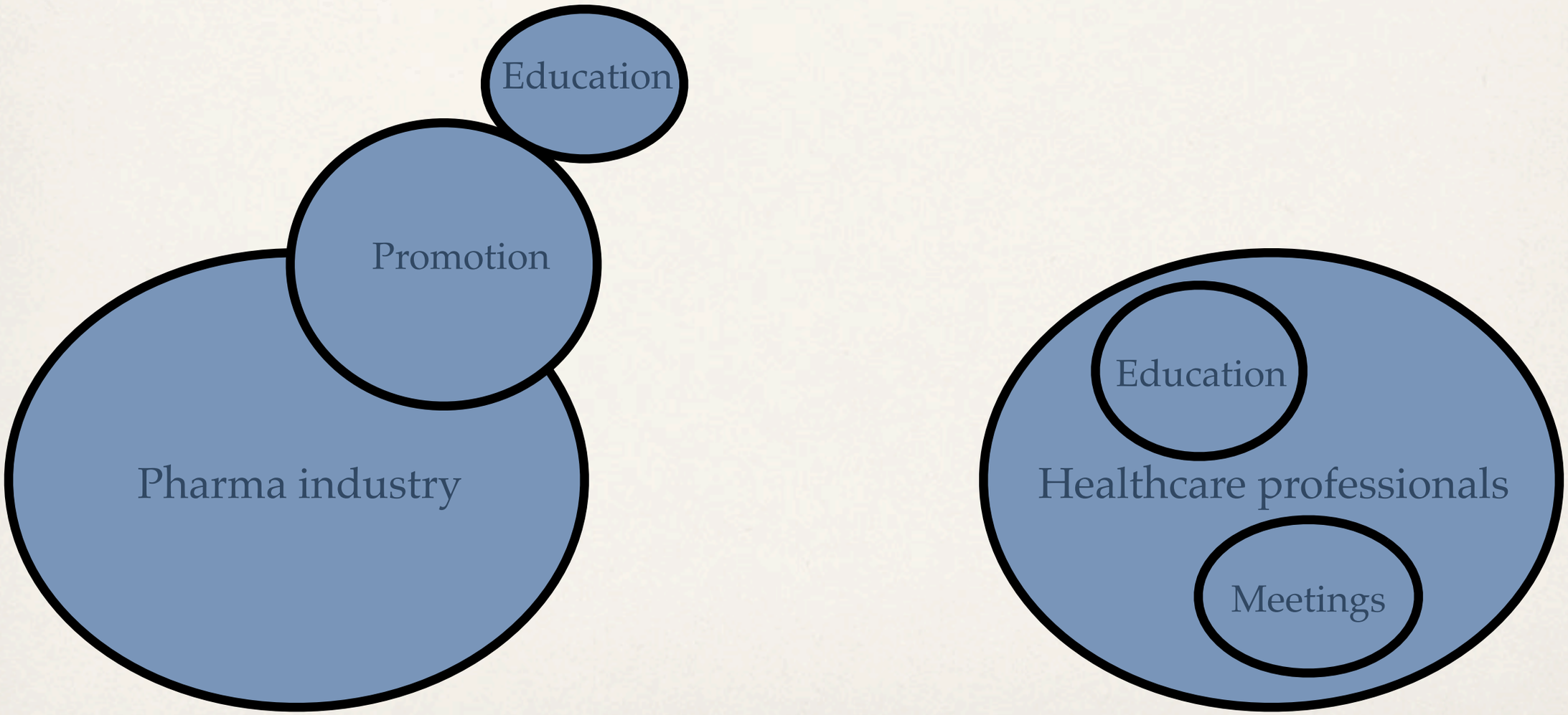




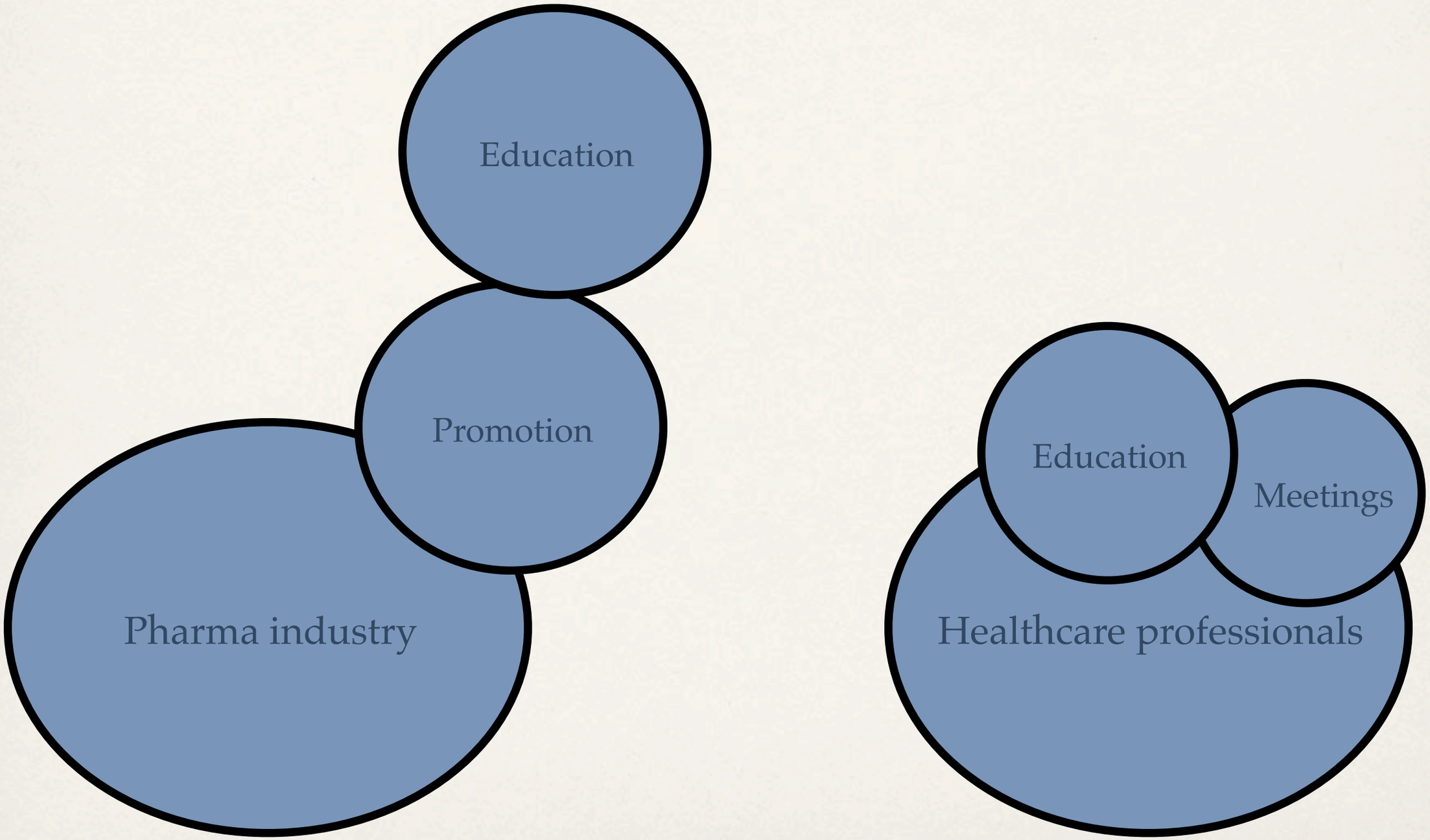




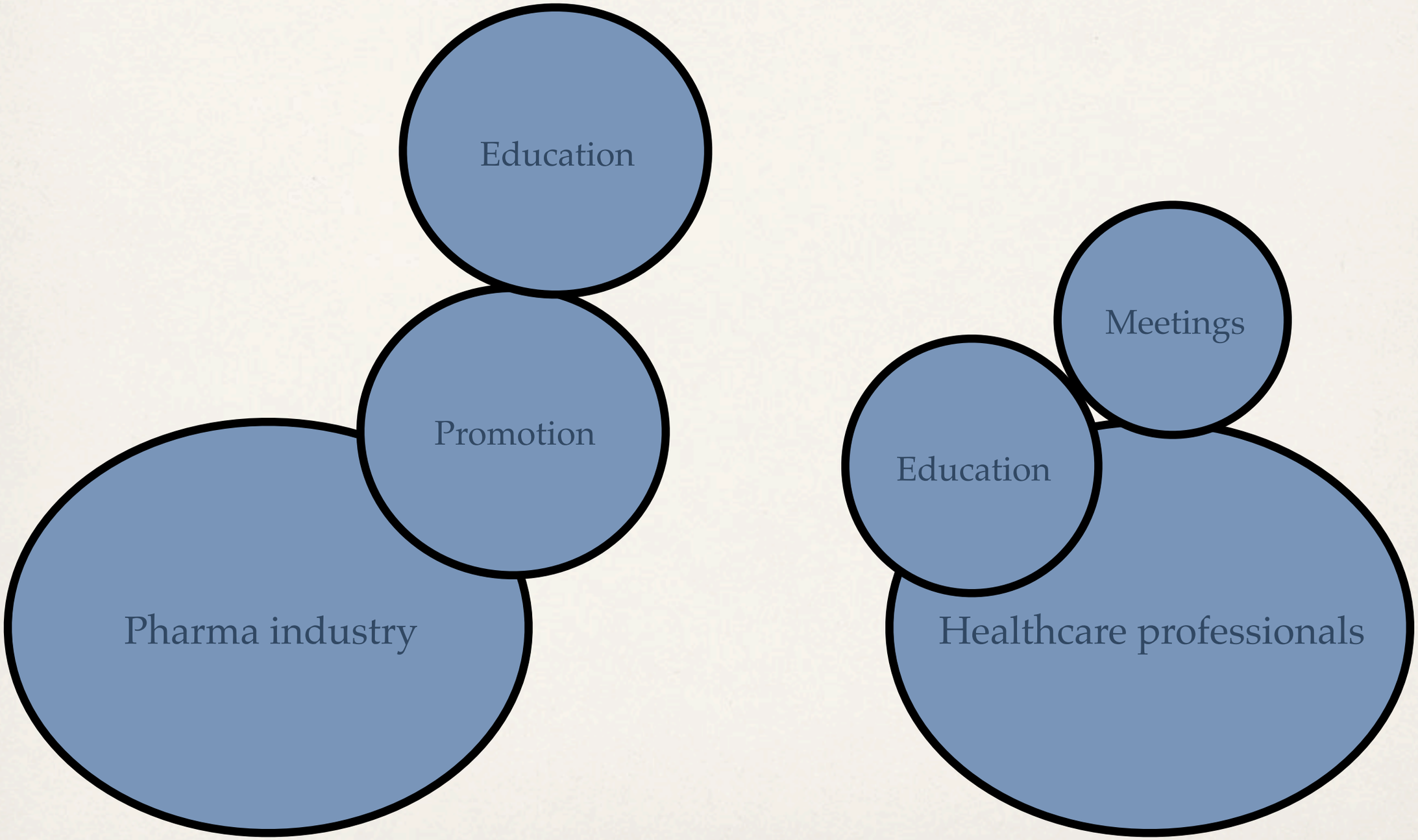
~30 years ago...


Education
Promotion
Pharma industry
Education
Healthcare professionals
Meetings

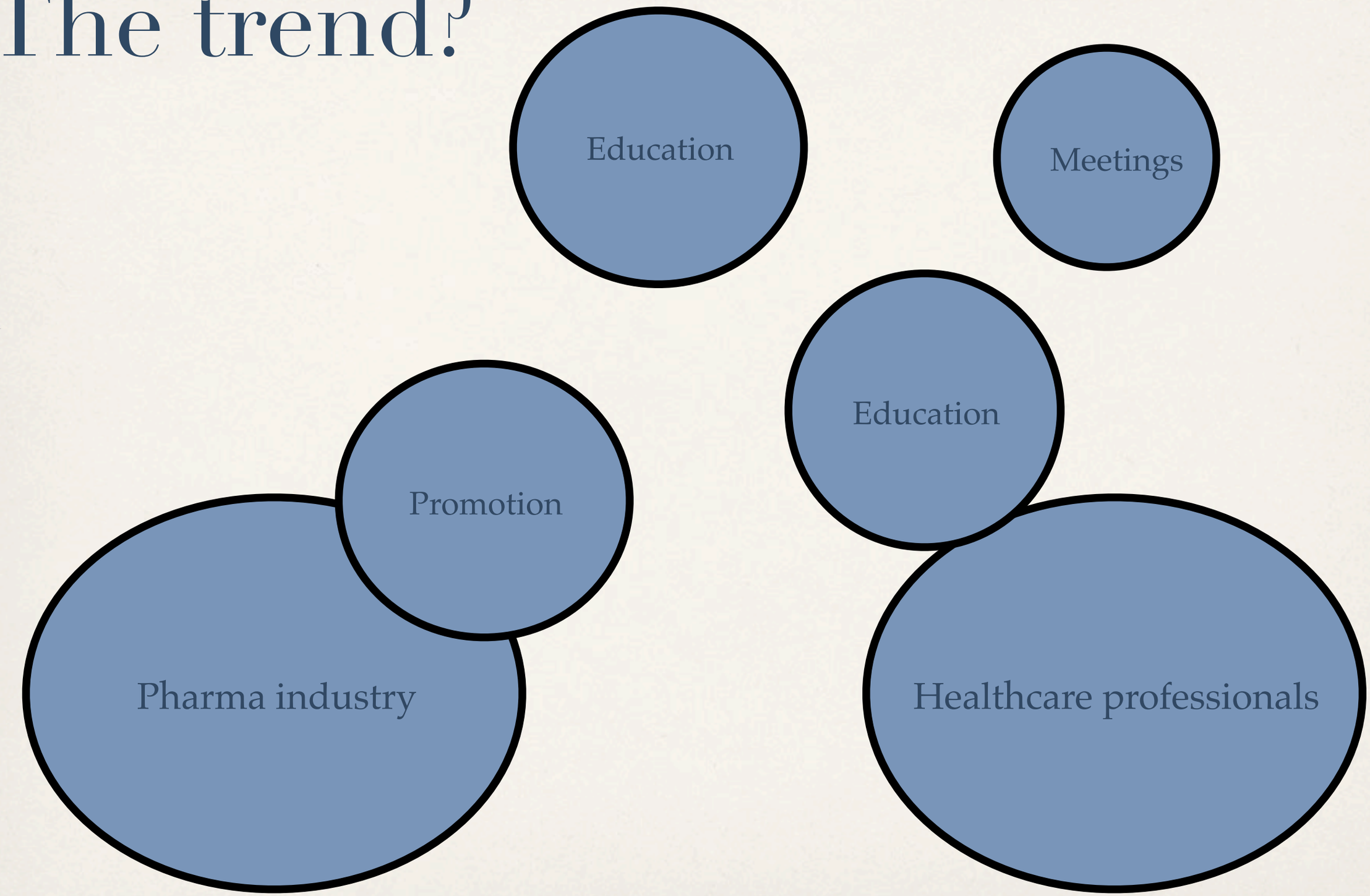
~20 years ago...


Education
Promotion
Pharma industry
Education
Meetings
Healthcare professionals

In recent years...



The trend?


Education
Meetings
Promotion
Education
Pharma industry
Healthcare professionals

The trend?

CME accredited

Education

Meetings

Education

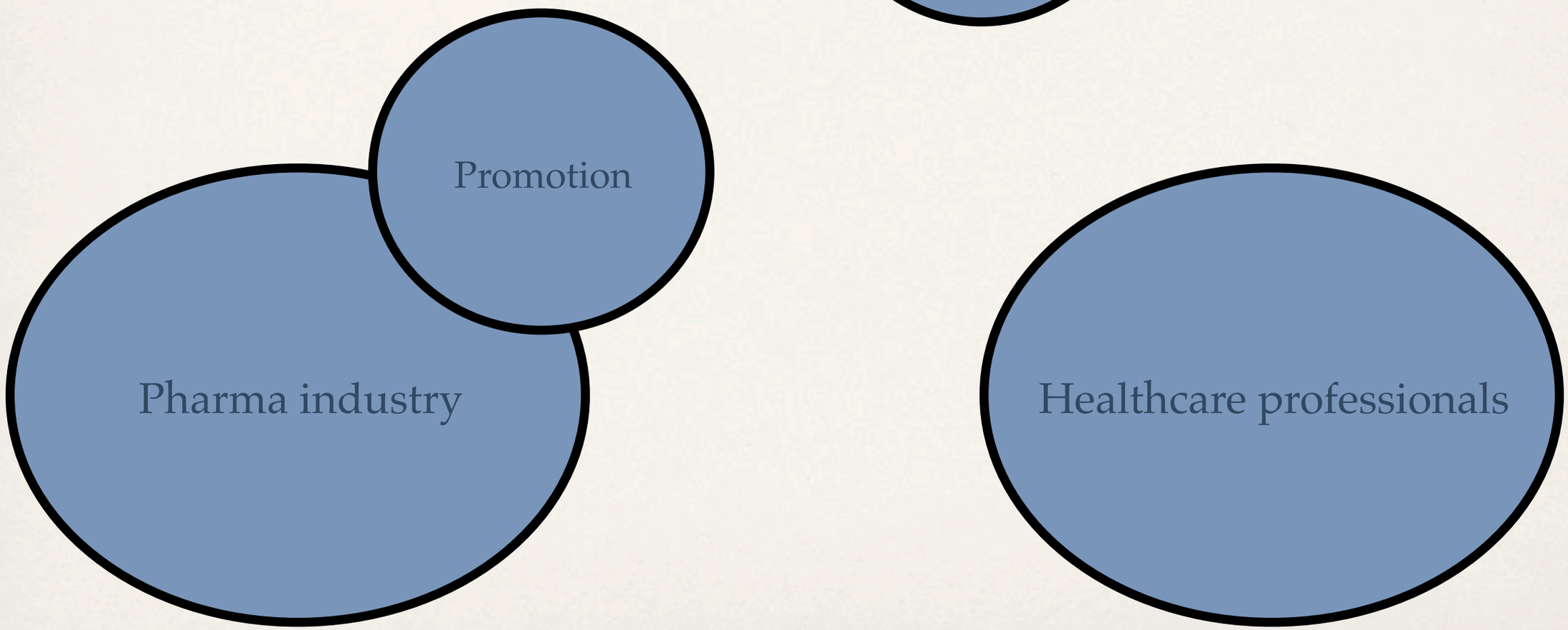
Promotion

Pharma industry

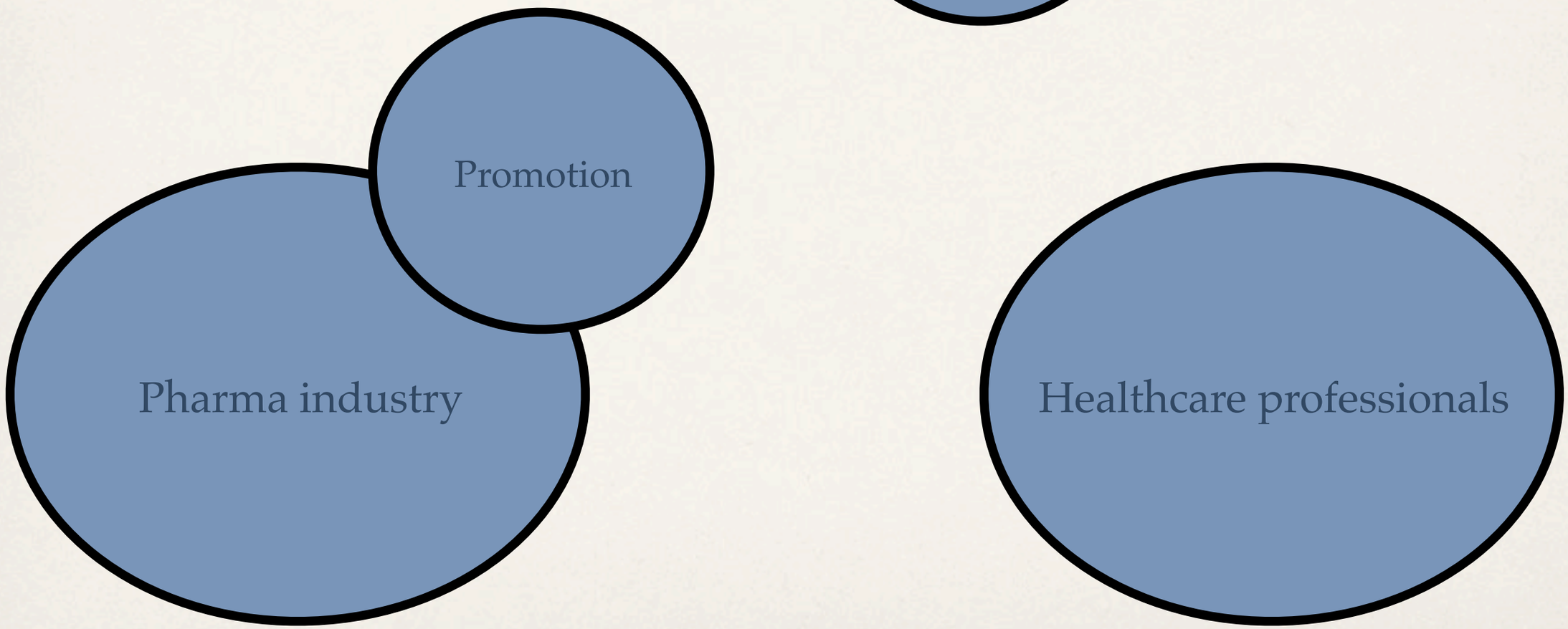
Healthcare professionals

Or even this?

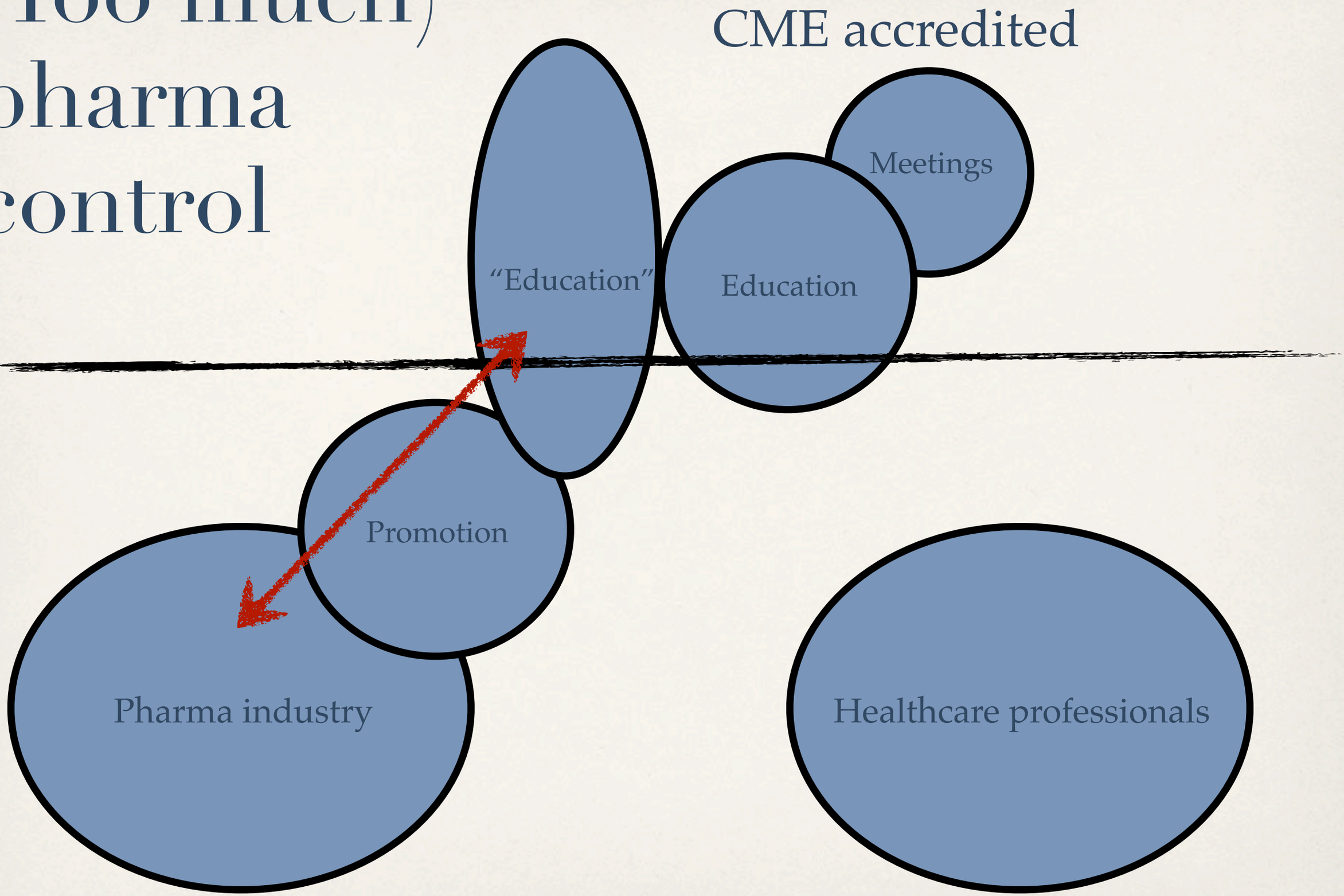
CME accredited



But when does this go wrong?



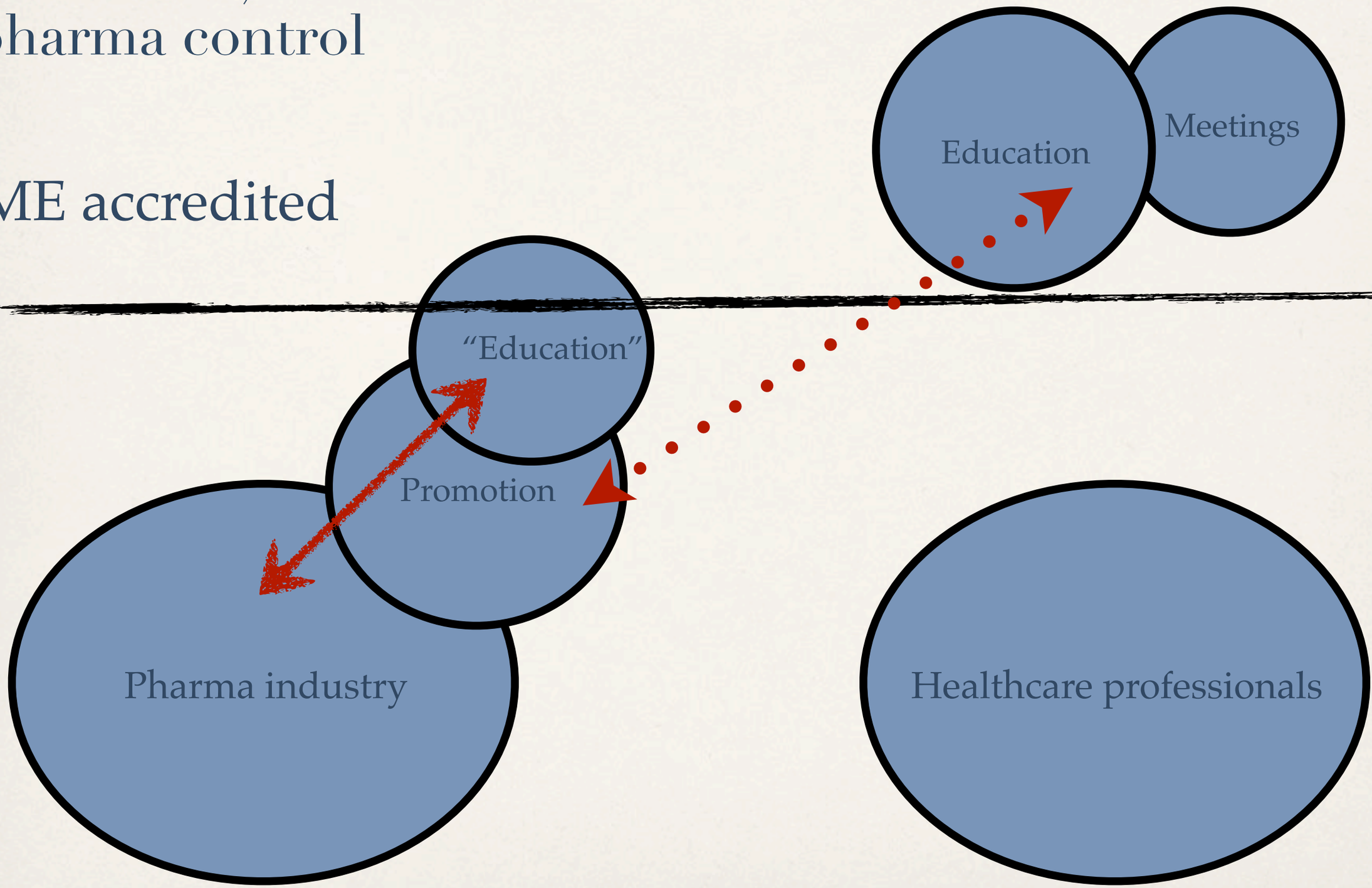
(Too much) pharma control



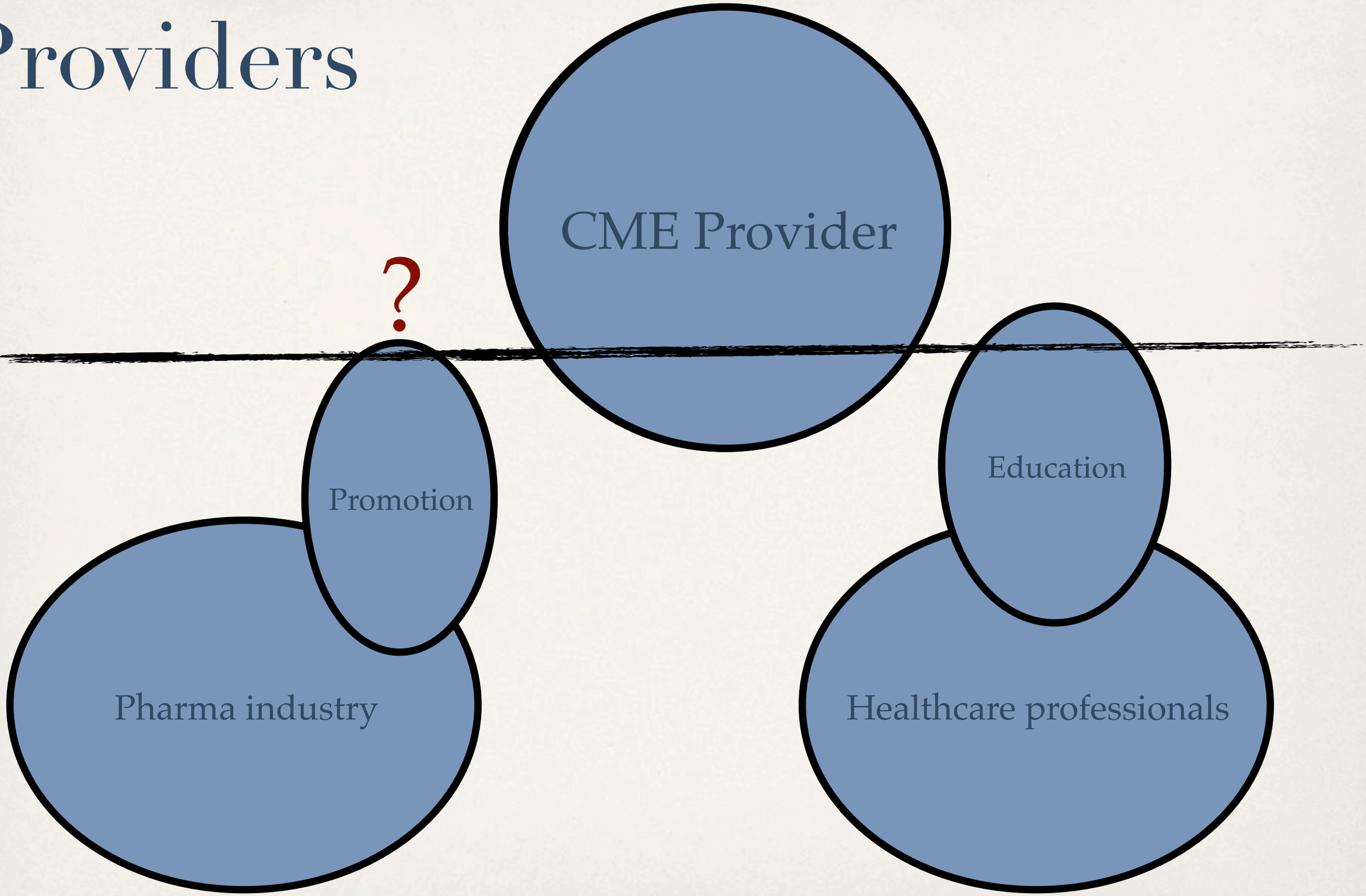
Poor Quality

(Too much)
pharma control

CME accredited



Providers


CME Provider
?
Promotion
Education
Pharma industry
Healthcare professionals

Providers

INDEPENDENT

CME Provider

THIRD PARTY

Promotion

Pharma industry

THIRD PARTY

Education

Healthcare professionals

2. Why the need for Guidelines?


MARE GIGLIO

CME rules to follow

- CME accreditation bodies - UEMS-EACCME, EBAC, ACOE etc. etc.
- Industry - very little in CME
- Providers ????

New UEMS-EACCME Guidelines

New UEMS-EACCME Guidelines

- 1999
- e-learning standards
- Version 1 (November 2010)
- Version 2 (November 2011 - implementation from 1 January)

UNION EUROPÉENNE DES MÉDECINS SPÉCIALISTES
EUROPEAN UNION OF MEDICAL SPECIALISTS

Association internationale sans but lucratif — *International non-profit organisation*

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F +32 2 640 37 30
info@uems.net

UEMS 2012 / 30

The Accreditation of Live Educational Events by the EACCME®

Adopted by the UEMS Council on 19th October 2012 in Larnaca (Cyprus)

Entry into force: 1st January 2013

Introduction

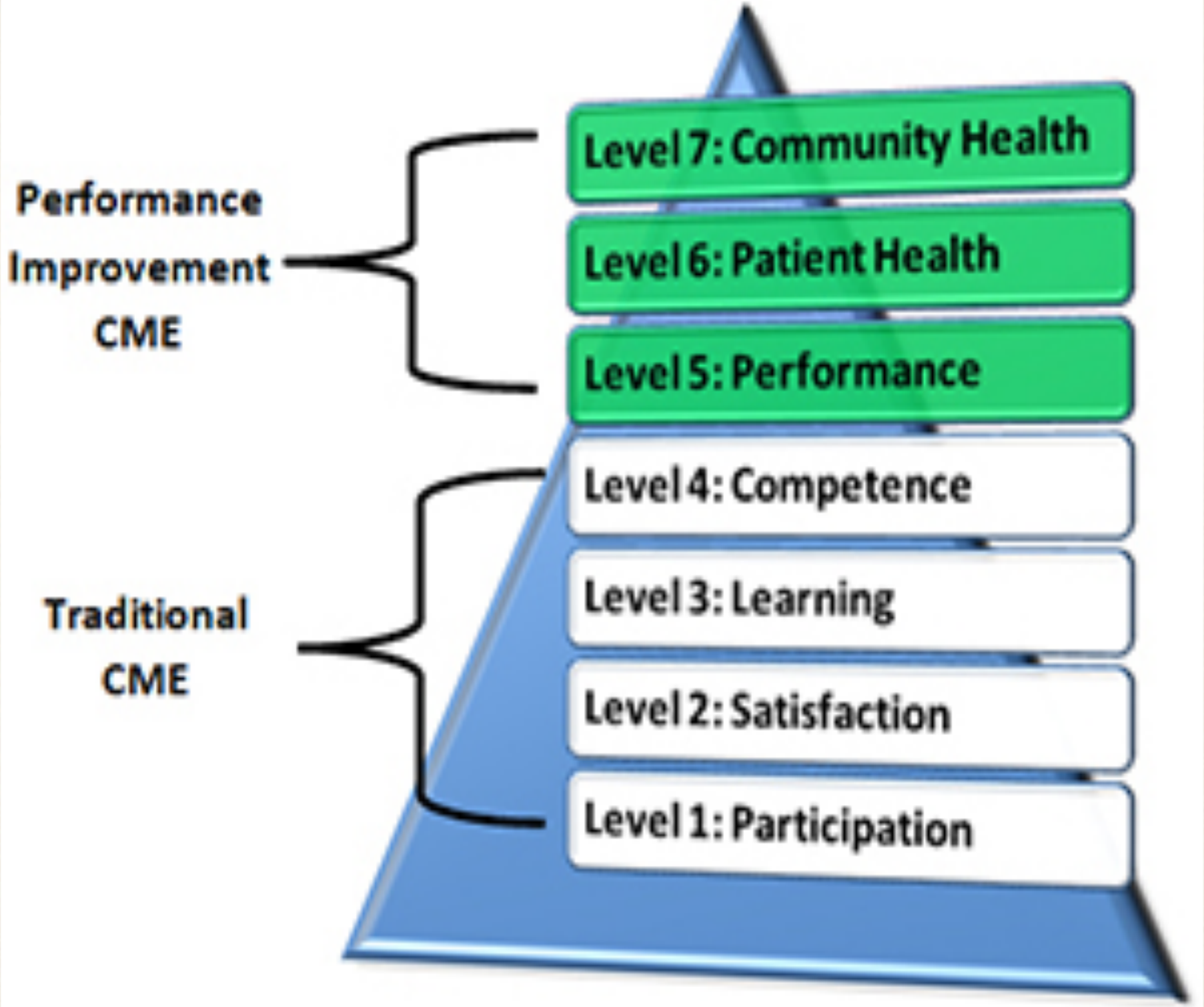
1) The European Union of Medical Specialists (UEMS) was founded in 1958 with the aim of representing the interests of specialist doctors at an international level. The UEMS is a non-governmental voluntary organisation comprising the national medical organisations that represent medical specialists in the European Union and in associated countries. With a current membership of 34 countries, and 39 specialist sections, the UEMS provides for the representation of approximately 1.4 million medical specialists working in Europe. The UEMS is

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 what relevant educational needs have been identified 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 where in a doctor's practice this will have an impact.
(Essential criterion)



*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.

Description of the Live Educational Event

14) *The Provider must provide the title of the LEE, its venue, date(s), and a clear description of the nature of the event.*

This must indicate whether the LEE will involve lectures, discussions, workshops and/or other educational methods, single or multiple sessions, and whether these will be sequential or in parallel. The EACCME® will consider applications for whole meetings, or, where these fulfil minimum time-based criteria (see paragraph 17), for specific components of a meeting. Separate applications for accreditation will be required for academic satellite symposia that are not part of the conference programme.

(Essential criterion)

15) *The LEE must be presented in a manner suitable for an international audience.*

The LEE will need to demonstrate that it can accommodate the educational needs of an international audience with the primary language determined by the composition of the audience and facilities available for interpretation as required. International terminology for procedures and therapeutic agents must be used.

(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 time for question and answer sessions; opportunities for audience participation; key-pad votes and discussion.

(Essential criterion)

Details of the Provider

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 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)

22) *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.*

The Scientific and/or Organising Committee

23) *The Provider must provide the name(s), job title(s) and contact details of the head, and all other members of the Scientific and/or Organising Committee.*
The person responsible for, or in charge of the committee responsible for, the planning of the scientific content of the LEE must be clearly identified.
(Essential criterion)

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

25) *The Provider must confirm that any actual conflicts of interest have been resolved .*

Funding of the LEE

29) The EACCME® will only consider for accreditation LEEs that fulfil specific requirements related to their funding. Accordingly, events provided by the pharmaceutical and medical equipment industries will not be considered for accreditation.

Promotional material

33) *All educational material must be free of any form of advertising and any form of bias* (see appendix 6).
The EACCME® will reject any application that, in its opinion, includes advertising of any product or company directly related to any educational material.

Review by Learners

37) *The Provider must provide a reliable and effective means for the Learners to provide feedback on the LEE, including the extent to which the educational objectives of the LEE were met. The Provider must commit to make available to the EACCME® a report on this feedback and on the Provider's responses to this.*

EACCME	EACCME weeks	Providers	Provider weeks
		Recommended time for submission of application	**18**
EACCME Office The application will be rejected at this stage if it is not complete or if payment has not been received	**0**	**Latest date for receipt of <u>fully</u> completed application** and confirmed payment of EACCME fee	**14**
Review process commences (application sent to reviewers)	**1**		**13**
EACCME Office (reminders sent to reviewers)	**5**		**9**
Processing time - Usually no more than 5 weeks for reviewers - Internal reconsideration - Amendment procedure (if necessary)	**6**		**8**
EACCME Decision	**10**	**Decision received**	**4**
Appeal decision (if activated)	**12**	**Appeal decision received**	**2**
	14	**LEE**	**0**

Summary for providers

- Appropriate education
  - Clear learning objectives, meets an identified unmet need, designed to be effective

- Fair balance
  - Independent of the sponsor, gives full clinical picture

- Transparency
  - Learner knows everyone involved, and their potential conflicts/biases

- Effectiveness
  - Post-activity evaluation against learning objectives

CMRO

Current Medical Research & Opinion Vol. 28, No. 11, 2012, 1861–1871

0300-7995
doi:10.1185/03007995.2012.738191

Article FT-0285.R1/738191

Original article

Setting CME standards in Europe: guiding principles for medical education

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International Medical Press, London, UK

Darren Gillgrass
Informa Healthcare, London, UK

Alisa Pearlstone
PCM Scientific, London, UK

Jack Torr
Communigen, Oxford, UK (Formerly with iS Academy, Farnham, UK)

Eugene Pozniak
Siyemi Learning, Manchester, UK

On behalf of the founding members of the Good CME Practice Group, an initiative of the European CME Forum: AXDEV Group; European Institute for Medical and Scientific Education; Haymarket; Informa Healthcare; International Medical Press; IntraMed Europe; KWHC; Medcon International; MedEd Global Solutions; PCM Scientific; Prime Oncology; Siyemi Learning http://www.gCMEp.eu

Abstract

Objective:
The requirement for formal Continuing Medical Education (CME) is growing in Europe with a concomitant focus on quality and independence of medical educational programmes, together with a need for measurable effects on patient outcomes. However, during this rapid evolution, it has become clear that there are misunderstandings and confusion amongst CME providers in relation to standard and regulations. To address this challenging situation, the Good CME Practice Group undertook an initiative to establish a set of standard core principles with a view to adoption by European CME providers and other key organisations involved in provision of CME programmes.

Methods:
The Good CME Practice Group developed four core principles relating to (a) appropriate education, (b) effective education, (c) fair balance and (d) transparency. In order to seek advice and input from peer groups and others involved in CME including accrediting bodies and medical societies, 93 representatives from these bodies were asked to complete a questionnaire and provide comments on the core principles. Participants for the consultation process were generated by a systematic search for European organisations with sections committed to medical education across all therapy areas and all key accrediting bodies. Following the consultation phases, the core principles were reviewed in light of responses and feedback and amended as appropriate.

What does wrong look like?

- Pharma control
- Contracts with faculty
- Supporter wants to attend the pre-meeting speaker briefing
- Reviewing content with intent to change it
- Any kind of “Control”

What does wrong look like?

- Faculty guidance
- Eminence-led programme development
- Chair wants to invite “friends” rather than suitable speakers
- Faculty wants 5* luxury
- Using funding for non-related uses

What does wrong look like?

- Providers
  - Not willing to take control or responsibility
  - Listening to pharma, instead of pharma listening to them
  - Not being aware of its own responsibilities

On whose authority are the Providers acting?

- EFPIA??
- CME accreditation body?
- Self-regulation – e.g. gCMEp
- Local legal obligations

Summary

What does 2013 offer?

- Accreditators giving guidance - sanctions
- Pharma clear understanding: use of agreed CME guidance
- Providers clear in their role and expectations
- Ultimately an alignment of objectives that are mutually compatible

Thank you.

- #6ECF, London, 13-15 November 2013

- www.europeanCMEforum.eu
- www.gCMEp.eu
- www.jecme.eu
- www.siyemi.org