After participating in this educational session, learners should be able to:

• Discuss what "compliance" means for medical meetings.
• Review the guiding principles behind the changing medical education environment.
• Differentiate compliance in regard to CME/CPD accreditation criteria and industry codes.
• Discuss the purpose of industry codes.
• Recognize the various compliance levels.
• Explain the continued challenges related to code complexities, inconsistencies, variability, changes, etc.

"Gee, mom...if he got all these from medical schools, why is he still PRACTICING?"
After participating in this educational session, learners should be able to:

• Discuss what “compliance” means for those offering CME/CPD.
• Apply the core/guiding principles behind the changing medical education environment.
• Differentiate compliance in regard to CME/CPD accreditation criteria and industry codes.
• Navigate challenges related to the complexities, variability, and changes encountered in international CME/CPD.
“Compliance”

I LOVE COMPLIANCE TRAINING
IT MAKES PEOPLE CRY

Compliance Is My Life.

I LOVE IT WHEN YOU FOLLOW THOSE
COMPLIANCE RULES.

I FIND YOUR LACK OF
COMPLIANCE
DISTURBING

EVERYBODY * LOVES * A COMPLIANCE PERSON

I ❤ Being Compliant
Compliance Challenges

• At the intersection of all stakeholders
• Moving and multiple targets
• Lack of clarity…”it depends”
• Not a level playing field
• Who’s checking anyhow?
• Internal and client education
• Business realities/limited resources
• Recognition of role of the provider
Navigating Compliance Waters
gCMEp Core/Guiding Principles

- Appropriate Education
- Effectiveness
- Balance/Independence
- Transparency
Appropriate and Effective Education

From pedigree to performance
From meeting planning to educational design
Learning and change
From disseminating information to improving care
Balance/Independence

CME activities must demonstrate balance, independence from commercial bias, and be objective and scientifically rigorous.

• Questioning role of industry
  • “Marketing in the guise of accredited education”

• Independent planning process
• Separation of promotional education/activities
  – Scientific/educational program
  – Physical activities
  – Conference materials
• Disclosure (faculty and support)
Do the right thing and Show that you’re doing it

- Documentation
- Disclosure
- Reporting
- Honesty
- Ethics
- Accountability
- Public trust

"Under disclosure rules, I'm required to tell you I own stock in the company whose drug I'm prescribing."
gCMEp Core/Guiding Principles

- Appropriate Education
- Effectiveness
- Balance/Independence
- Transparency
Does It Matter Which Set of Rules?

- CME/CPD Accreditation Criteria
- Industry codes
CME/CPD Accreditation Criteria

- Performance gaps
- Needs assessments
- Learning objectives
- Interactive formats
- CME to CPD
- Expert Faculty
- Disclosure and COI resolution
- Standards for commercial support
- Independence (role of industry)
- Evaluation – credit – certificate
- Outcomes
Industry Codes – What?

- Ethical standards and principles for interactions with healthcare professionals

- Broad scope
  - Marketing and promotional materials
  - Samples and gifts
  - Off-label
  - Sponsorship of HCPs
  - Meetings and events
  - And much more…

- International, National, Company, Healthcare Professionals
Industry Codes – Why?

European cardiologists recognize contribution of medical device industry to improving patient care

Ethica award acknowledges role of safe, innovative cardiovascular devices in changing and saving patient lives

Fine for False Marketing

Sep 2, 2009 1:11 PM CDT
“Any practice that might create confusion about the real scientific and educational purpose of scientific events sponsored by industry or to which industry sponsors HCPs should not be tolerated.”

European Federation of Pharmaceutical Industries and Associations (EFPIA)
Which Set of Rules?

- CME/CPD Accreditation Criteria
- Industry codes
gCMEp Core/Guiding Principles

- Appropriate Education
- Effectiveness
- Balance/Independence
- Transparency
Company ABC issues a request for proposals for CME activities that address educational gaps relating to disease X. The RFP document outlines educational needs and desired educational learning objectives for CME activities.

Which core/guiding principles? Which set of rules? What would you do?
Case Study: Lady (Bad) Luck

- Singapore international event
- Venue renovations delayed
- Move to Sands Convention Center
- Casino property

Which core/guiding principles?
Which set of rules?
What would you do?
Case Study: Faculty Agreements

• Unrestricted educational grant by Pharma ABC.
• As CME provider, you are recruiting faculty under the direction of the Programme Director.
• You receive an email from the Pharma ABC requesting that all faculty sign the Pharma ABC contract outlining terms of the faculty involvement.

Which core/guiding principles?
Which set of rules?
What would you do?
Case Study: A Night on the Town

• End of congress
• Networking dinner
• Milanese nightclub
• Optional w/ additional fee
• Congress website social programme

Which core/guiding principles?
Which set of rules?
What would you do?
Navigating Compliance Waters

- Regulated healthcare environment
- Which set of rules
- No compliance guarantee or checklists
- Concepts, ethos, and guiding principles
- Resources
  - Accrediting bodies
  - Industry associations
  - Stakeholder organizations (IPCAA, gCMEp Group, etc.)
  - You!
- Compliance Darwinism
- With change comes opportunity
Thank you!

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