



# CME

## *The Role of Biomedical Industry in Postgraduate Medical Education / CME in EMEA*

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***“The complacent company is a dead company.  
Success today requires the agility and drive to constantly rethink,  
reinvigorate, react and reinvent”***

**- Bill Gates -**



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1. **Situation Analysis & Dynamics**
2. **J-C EMEA Business Integrity Framework**



# SITUATION ANALYSIS

## USA versus EMEA



USA <sup>1,2</sup>		EMEA <sup>3</sup>
<ul style="list-style-type: none"><li>✓ CME required to practice medicine in most States</li><li>✓ 99% of physicians actively engage in financing and obtaining minimum annual CME credits</li></ul>	<b>Mandatory</b>	<ul style="list-style-type: none"><li>✓ Mandatory in many "EC" countries (20); voluntary in others</li><li>✓ Non-existing in most non-EC countries (nearly 90)</li><li>✓ Mutual recognition remains an issue</li></ul>
<ul style="list-style-type: none"><li>✓ One regulatory body : Accreditation Council for Continuing Medical Education (ACCME®)</li><li>✓ Strict and established criteria</li></ul>	<b>Accreditation</b>	<ul style="list-style-type: none"><li>✓ Several types of CME accreditation bodies</li><li>✓ No consistent accreditation across Europe</li><li>✓ Criteria dependant on accreditation body</li><li>✓ Varying roles of Medical Societies as CME providers</li></ul>
<b>US CME strictly governed</b>		<b>CME landscape in Europe, patchwork of governance</b>

Based on: 1. IPCAA, CME in the US, CME Workshop Frankfurt 2006  
2. ACCME®, website last visited 21<sup>st</sup> October, 2008  
3. E. Pozniak, The Changing Face of CME in Europe: Where are we now?, November 2007



# SITUATION ANALYSIS

## USA versus EMEA

	USA		EMEA	
<ul style="list-style-type: none"><li>✓ Separation funding source and ME activity</li><li>✓ HCP support for attending ME events → not allowed</li></ul>	<b>BMI Involvement</b>	<ul style="list-style-type: none"><li>✓ Sponsorship national and European congresses</li><li>✓ Sponsorship of 60 – 80% of participants</li><li>✓ EMEA postgraduate education model not viable without BMI</li><li>✓ No or very little monitoring in the field</li></ul>		
<ul style="list-style-type: none"><li>✓ Important role of developing unbiased accredited ME</li><li>✓ Remain independent → Call for disclosure of any (financial) conflict of interest</li></ul>	<b>CME providers</b>	<ul style="list-style-type: none"><li>✓ Medical Societies</li><li>✓ ACCME accredited providers (US model)</li></ul>		



## DYNAMICS

### *External Drivers of Self-Regulation within BMI*



#### External Drivers

- ✓ Providing/paying for ME for non-US HCPs → allowed and common practice in EMEA, but considered as value exchange  
→ ***FCPA and national anti-bribery laws apply (bribery is a criminal act)***
- ✓ US authorities stepped up FCPA enforcement
- ✓ Particular issue in health care sector:  
HCPs in public hospitals and government-owned/controlled hospitals may be considered government officials as well as regulators and payers
- ✓ Sunshine Act in US: Transparency and mandatory publishing of payments to HCPs
- ✓ Similar legal initiatives at national level in EMEA



## DYNAMICS

### *Internal Drivers of Self-Regulation within BMI*



#### Internal Drivers

- ✓ “Building trust” critical cornerstone of new business models
- ✓ Strong trend towards industry self-regulation
- ✓ EFPIA Code Update: Broadening from “Promotion” to “Interactions with ...” and in scope individuals (e.g. patient representatives)
- ✓ A never-seen roll-out/implementation of company ethical codes, business integrity guides and related monitoring/testing and change management programs
- ✓ CME funding by BMI is moving from marketing budgets to medical education/affairs departments (including decision making and ownership)



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1. **Situation Analysis & Dynamics**
2. **J-C EMEA Business Integrity Framework**





# J-C EMEA BUSINESS INTEGRITY FRAMEWORK

## Case: Medical Education Policy

### Define Business Integrity concepts & principles

✓ Intent

✓ Transparency

### HCBI Guide & SOPs

Translation of industry laws, regulations and guidelines into a company-specific set of policies & processes → *Case: J-C EMEA ME Policy*

### Training & Engraining

✓ Trainings

✓ e-Learnings

✓ Presentations

### Implementation & Control

✓ Change Management Programs

✓ Monitoring & Testing

✓ Documentation



## J-C EMEA BUSINESS INTEGRITY FRAMEWORK

### Case: Medical Education Policy – Definitions

#### Medical Education



Any kind of activity primarily **intended** to benefit Health Care Professionals, the scientific community or patients through the dissemination of information or the demonstration of treatments/procedures and that contributes to, or advances the practice of medicine.

#### Promotion



Any kind of activity that is primarily **intended** to promote the benefits, features and usage of J&J company products.

**Medical Education according to strict and mandatory J-C EMEA policies**



# J-C EMEA BUSINESS INTEGRITY FRAMEWORK

## Case: Medical Education Policy – Overview

	MEDICAL EDUCATION	PROMOTION
Plan	✓ Annual BP	✓ Annual BP
Program Intention	<ul style="list-style-type: none"> <li>✓ To benefit customers and patients</li> <li>✓ Provide research info that contributes to or advances the practice of medicine</li> <li>✓ Free of ROI calculation</li> </ul>	<ul style="list-style-type: none"> <li>✓ To promote benefits, features &amp; usage of company products</li> <li>✓ ROI calculation</li> </ul>
Program Content	<ul style="list-style-type: none"> <li>✓ Developed with and endorsed by independent Scientific Third Party</li> <li>✓ Owned by authors</li> <li>✓ Can include data on compounds / indications under development</li> </ul>	<ul style="list-style-type: none"> <li>✓ Owned by the Company</li> <li>✓ Within label</li> </ul>
Program Approval	✓ Follow medical education development and approval process	✓ Follow promotional materials approval process
Budget	✓ MAF (managed by Med Ed Dpt)	✓ Marketing
Expense Reimbursement	✓ Travel & lodging reimbursement is allowed	✓ No travel & lodging reimbursement



## J-C EMEA BUSINESS INTEGRITY FRAMEWORK

### Case: Medical Education Policy – Programs & Materials



#### Content

- ✓ Info contributing to or advancing the practice of medicine
- ✓ Info regarding safety / efficacy, treatments or diseases
- ✓ Objective, unbiased and balanced

#### Ownership

- ✓ Developed with / endorsed by independent Scientific Third Party

#### Branding

- ✓ No branding elements or product-related promotional messages
- ✓ Company branding: with support of Correct Legal Entity” and logo


#### Dissemination

- ✓ To the audience
- ✓ Can be provided upon unsolicited request (via Medical Information processes & department)



## J-C EMEA BUSINESS INTEGRITY FRAMEWORK

### Case: Medical Education Policy – Development & Organisation

	<b>Accreditation</b>	✓ CME Accreditation must be sought from Official Body
	<b>Budget</b>	✓ Must reside outside Sales & Marketing ✓ Program must be free of ROI calculations
	<b>Venue</b>	✓ Must be suitable (i.e. not holiday resort, no deluxe hotels)
	<b>Arrangements</b>	✓ Arrangements with speakers & vendors are subject to written agreement (signed by both parties)



## J-C EMEA BUSINESS INTEGRITY FRAMEWORK

### *Special Focus on ME – Policies: Sponsorship & Payments*



## Sponsorship & Payments

### Disclosure

- ✓ Sponsorship must be clearly stated (pre-, during and post-event)
- ✓ Content of presentations owned by authors

### Selecting Participants

- ✓ Candidate profiles to be made for each event
- ✓ Selection and approval of participants outside Sales & Marketing

### Amounts

- ✓ Payment for services provided: Fair Market Value
- ✓ Hospitality: Modest
- ✓ Travel: Reasonable = same as for employees