



Global Compliance Benchmarking Survey 2013

- Initial Trends and Highlights -

CLIFFORD
CHANCE

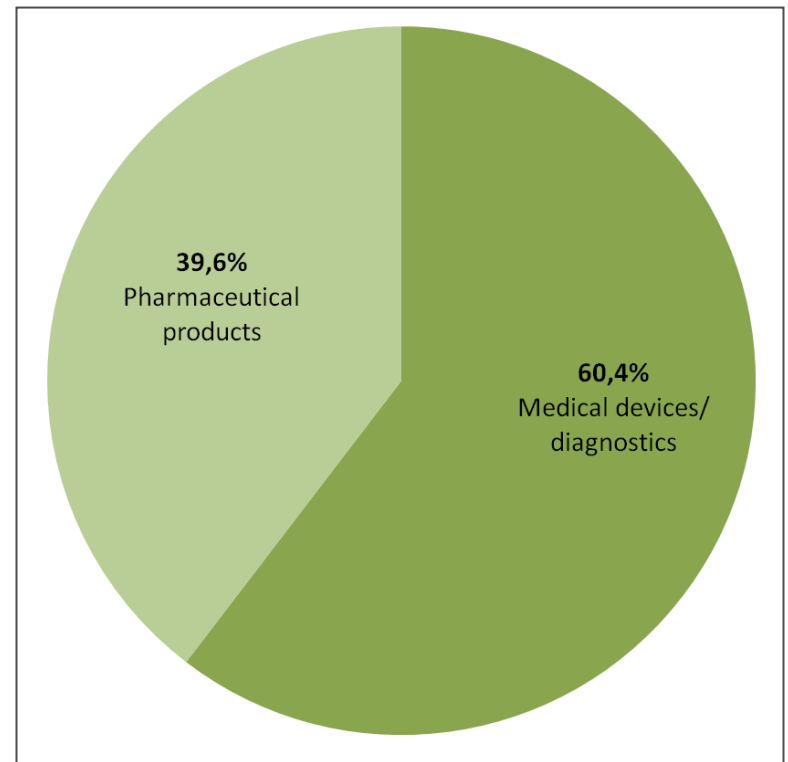
Dr. Peter Dieners

Scope and methodology

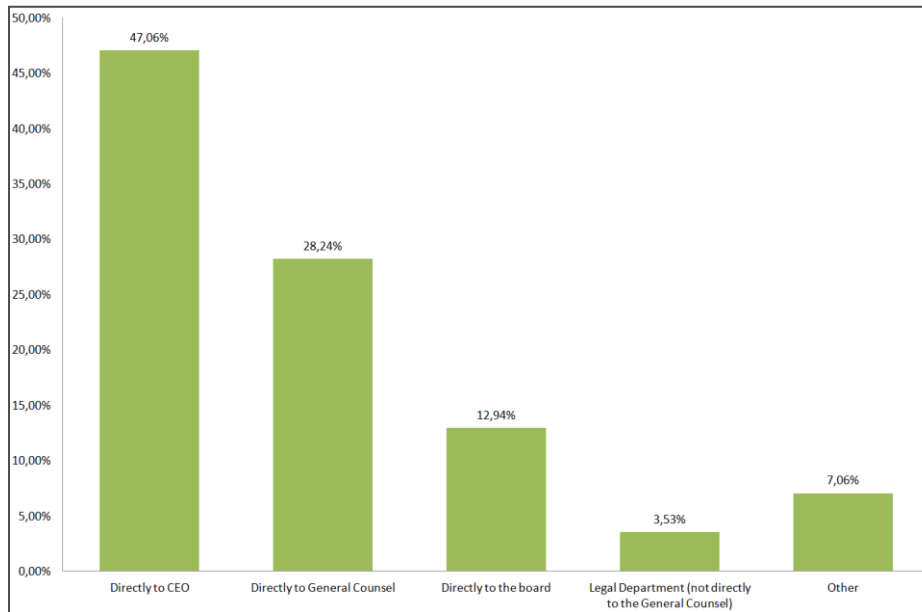
- Benchmark Survey sponsored by
 - AdvaMed
 - BVMed
 - edma
 - ETHICS
 - Eucomed
 - LEEM and
 - FSA
- Conducted in April/May 2013
- Roleed out as an cross-atlantic electronic survey
- Approached contacts within medical device and pharmaceutical organisations
- 59 questions
- 102 respondents
- Confidential survey-data was aggregated, not linked to individuals/companies

Covered product markets

Responses	Frequency
Medical devices/diagnostics	60,4%
Pharmaceutical products	39,6%

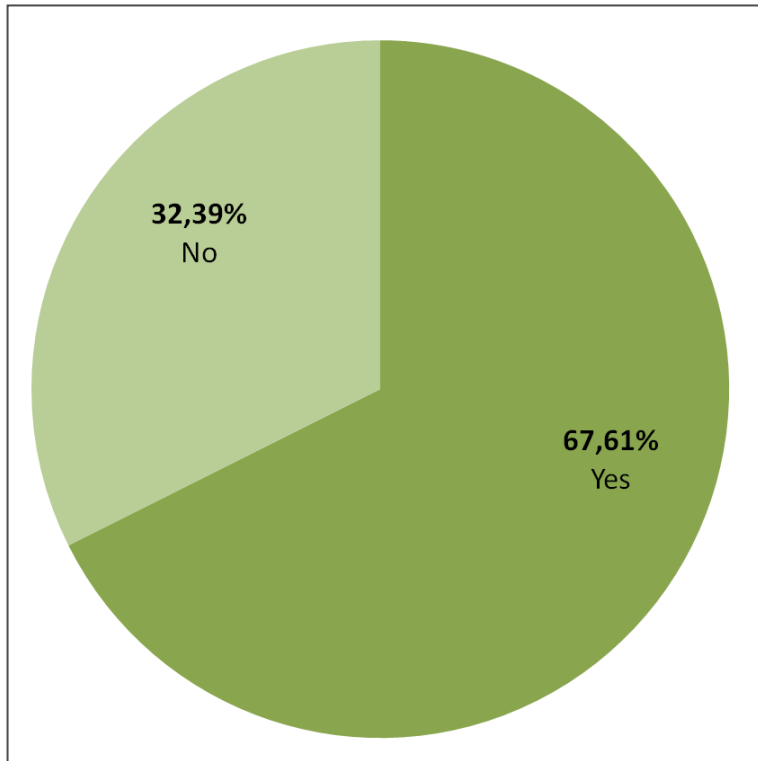


Reporting lines of Chief Compliance Officers



Responses	Frequency
Directly to CEO	47,06%
Directly to General Counsel	28,24%
Directly to the board	12,94%
Legal Department (not directly to the General Counsel)	3,53%
Other	7,06%

Written guidelines on the delegation of compliance responsibilities (organizational structure)



Responses	Frequency
YES	67,61%
NO	32,39%

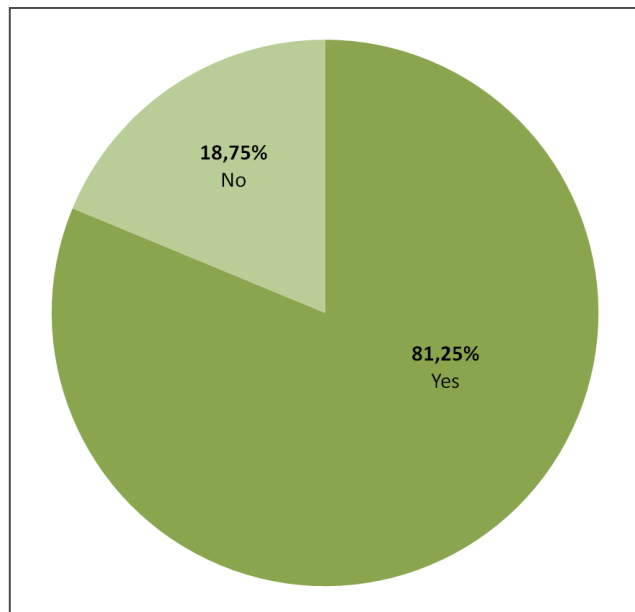
Compliance KPIs and bonus payments

Responses	Count 204
training metrics	34
database to report on compliance incidents	33
number/type of investigations, hotline calls	32
expense reporting violations	17
measurement of action plan developed, completed	15
metrics for diligence on vendors	15
metrics for committee activities	14
self assessments by business units	14
track number of contracts reviewed	14
tracking of patient complaints handled and resolved	14
internal	1
Risk Management	1

Responses	Frequency
No	83,34%
Complying with our company code of conduct (capturing all compliance principles) is a precondition for any bonus payout) while in high risk countries/region compliance counts for 20% of the bonus value for 2013.	5,56%
No KPI. Bonus are paid by judgement	5,56%
Yes, it is a factor in determining some individual's bonuses	5,56%

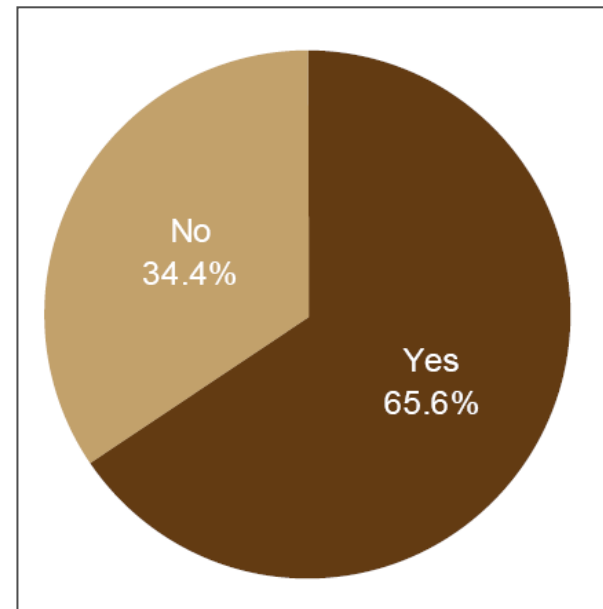
Establishment of policies regarding Fair Market Value (FMV) for services provided by HCP

2013



Responses	Frequency
YES	81,25%
NO	18,75%

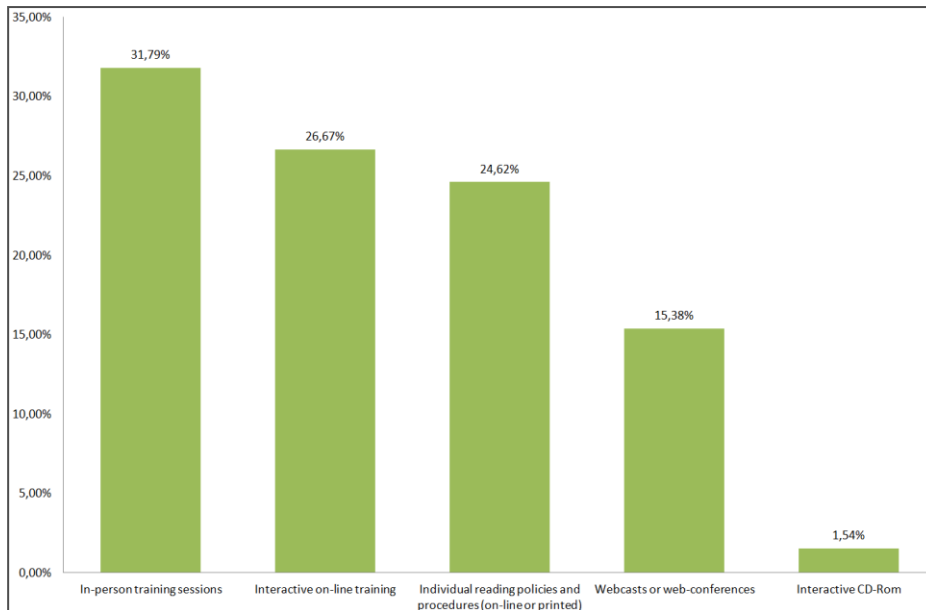
2007/08*



Response	Frequency
Yes	65.6%
No	34.4%

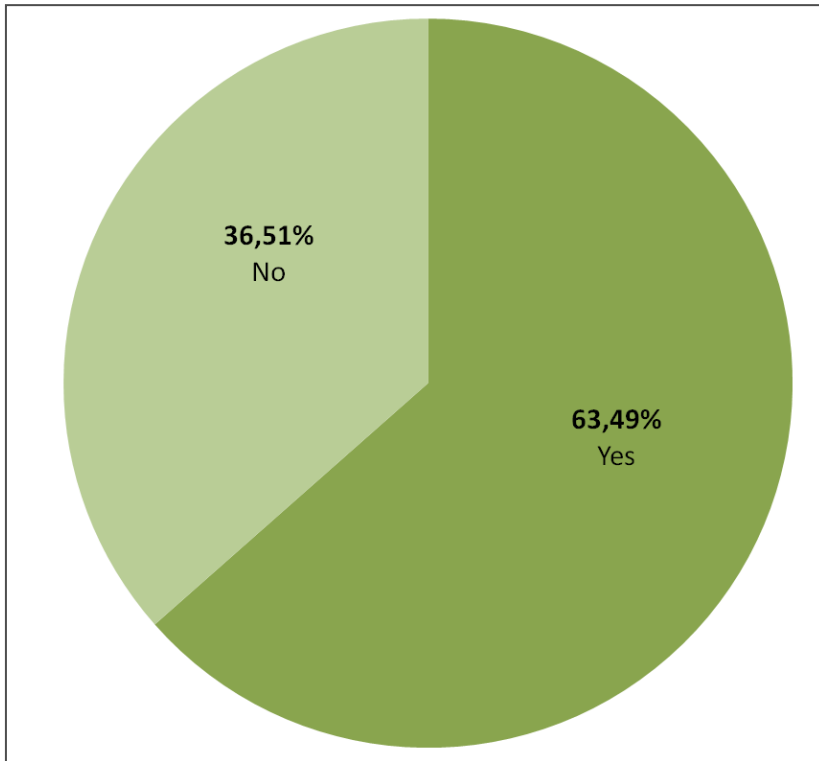
*PwC
Compliance
Survey 2007/08

Delivery methods used for compliance trainings



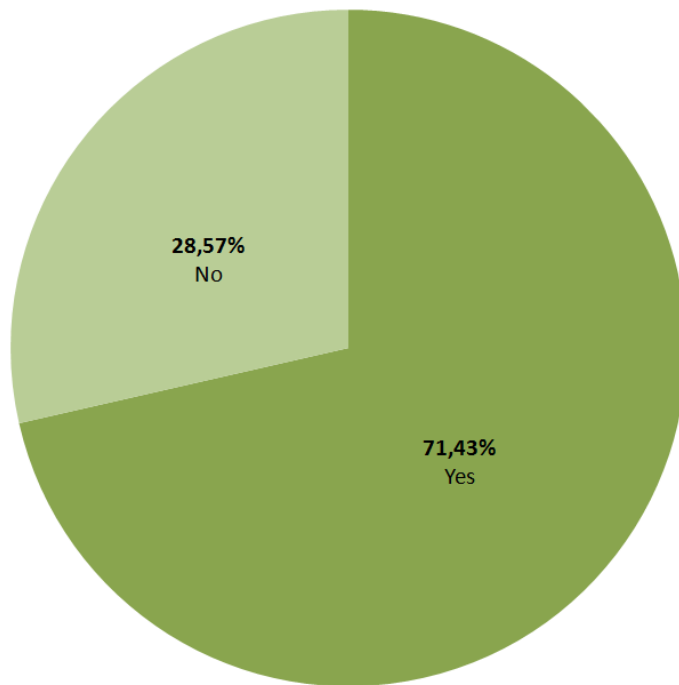
Responses	Count	Frequency
	195	
In-person training sessions	62	31,79%
Interactive on-line training	52	26,67%
Individual reading policies and procedures (on-line or printed)	48	24,62%
Webcasts or web-conferences	30	15,38%
Interactive CD-Rom	3	1,54%

Establishment of Monitoring & Auditing Guidelines



Responses	Frequency
YES	63,49%
NO	36,51%

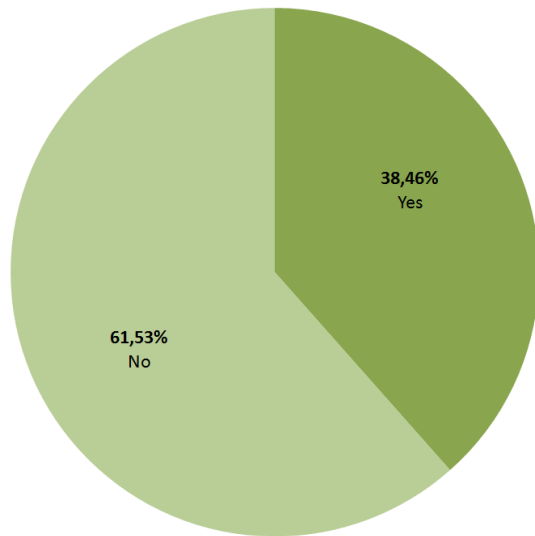
Proactive plans to disclose payments – Pharmaceutical Companies



Responses	Count	Frequency
	14	
YES	10	71,43%
NO	4	28,57%

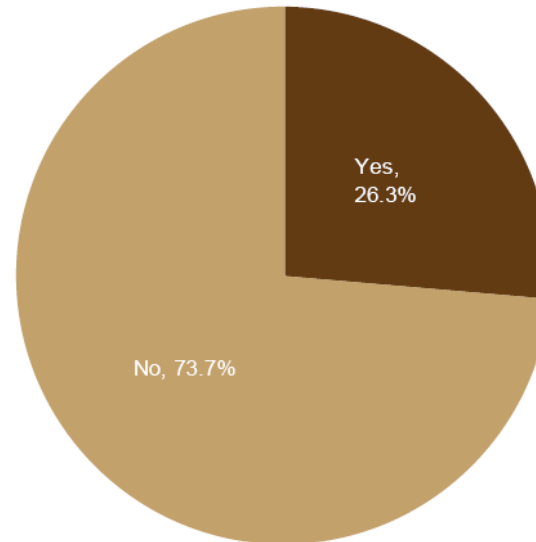
Proactive plans to disclose payments – Medical Device Companies

2013



Responses	Count	Frequency
	26	
YES	10	38,46%
NO	16	61,53%

2007/08*



Choice	Number of Votes per Option	% of Total Votes cast
Yes	5	26%
No	14	73%

*PwC
Compliance
Survey 2007/08

Top Compliance priorities – content & regional

Responses	Count 122	Frequency
Distributor relationships	30	24,59%
FCPA program	25	20,49%
Due diligence programs	24	19,67%
International Ethics Code	15	12,30%
Regulatory issues / approvals	8	6,56%
Third parties (e.g. CROs)	8	6,56%
Other	12	9,83%

Responses	Count 154	Frequency
Asia - Pacific	39	25,32%
Europe	39	25,32%
Middle East / Africa	26	16,88%
United States	23	14,94%
Mexico	12	7,79%
Other	15	9,75%

Initial survey take aways

■ Organization

- Reporting lines to CEO or to General Counsel
- Dominance of legal background
- Core responsibilities of CCO: Education, policies, interactions with HCPs and government officials
- Lack of written guidelines on the compliance organization as such (nearly 1/3)
- Multitude of sources/tools to address compliance issues
- No bonus payments to reward compliant behaviour

Initial survey take aways

■ Policies

- Written Policies and Procedures are standard
- Policies are either based on Eucomed/EFPIA codes (75%) or on local codes (25%)
- Increased establishment of explicit fair market value policies

■ Training

- More than 50 % are training sales representative once per year or more, but 50 less or without fixed intervals
- Content of compliance training covers all aspects of the relevant codes equally

Initial survey take aways

■ Monitoring and Auditing

- Lack of Monitoring & Auditing Guidelines (more than 1/3)
- No increase of audit frequency since 2007/08 survey

■ Top Compliance priorities

- Relationships to third parties are on the top of the agenda
- Asia-Pacific & Europe are on the agenda



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