Benchmarking Compliance for the Healthcare Industry

What every pharmaceutical and medical device company needs to know in 2013

November 2013

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Healthcare in the Spotlight

The global healthcare sector is facing more compliance challenges than ever before . . .

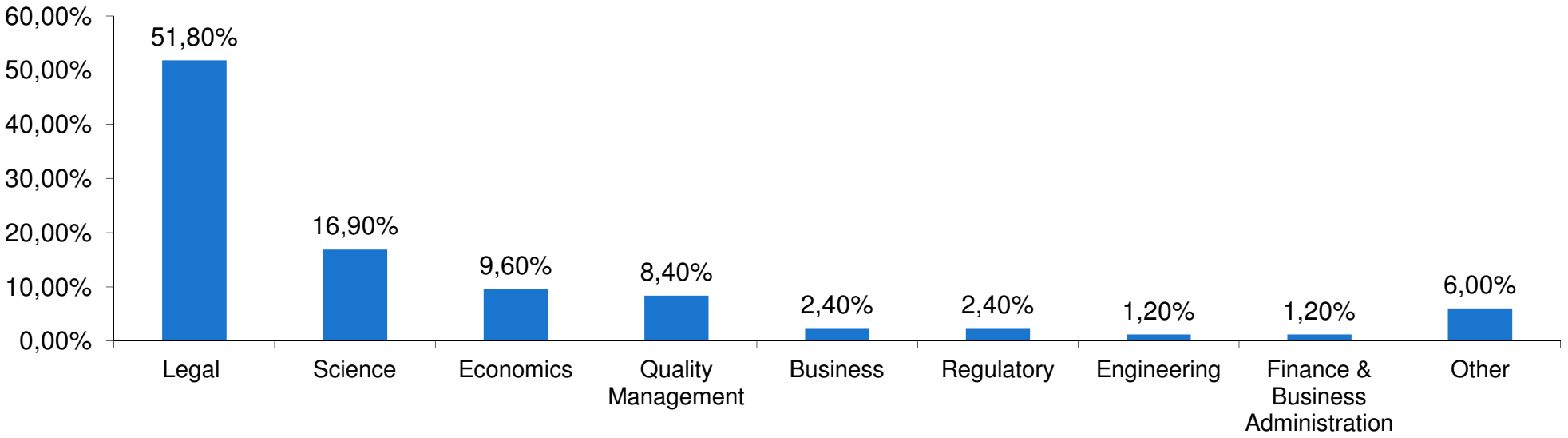
. . . from ongoing changes to healthcare laws throughout the world to the recent wave of high-profile bribery investigations in China . . .

. . . healthcare companies need to make sure that compliance is at the forefront of their business planning.

Helping the industry identify benchmarks

- To assist healthcare companies with this challenge, AdvaMed, Bvmed, edma, ethics, Eucomed, and FSA, in conjunction with Clifford Chance, created a survey to provide industry benchmarks regarding compliance-related practices.
- We distributed the survey to members of AdvaMed, Eucomed, and ethics during the spring of 2013 in an effort to obtain broad participation from the both the medical device and pharmaceutical industries.
- 102 responded to the survey on an anonymous basis; 60.4% from the medical device industry and 39.9% from the pharmaceutical industry.
- The results, which were compiled by Clifford Chance, covered the following compliance topics:
  - the structure and role of the compliance function within healthcare companies;
  - compliance policies, procedures, and practices;
  - training;
  - monitoring and auditing; and
  - top compliance priorities.

Educational background of respondents



Response	Frequency
Legal	**51,8%**
Science	**16,9%**
Economics	**9,6%**
Quality Management	8,4%
Business	2,4%
Regulatory	2,4%
Engineering	1,2%
Finance & Business Administration	1,2%
Other	6,0%

The structure and role of the compliance function within healthcare companies

CCOs have wide-ranging responsibilities

- Areas of responsibility include traditional compliance areas such as education and training, policies and procedures, and monitoring and auditing.
- Interactions with healthcare professionals (HCPs) and the government also top the list of CCO responsibilities.

Q: What is the scope of the Chief Compliance Officer's responsibility?

Response	Count
Compliance Education & Training	**74**
Compliance Policies & Procedures	**71**
Interactions with Healthcare Professionals	**69**
Compliance Monitoring & Auditing	65
Interactions with Government Officials	61
Compliance Investigations	57
Risk Management	35
Anti-Trust / Tendering	30
Privacy	29
FDA (or to the OUS equivalent) Compliance (e.g. quality and labelling)	27
Data Security	20
Project	1

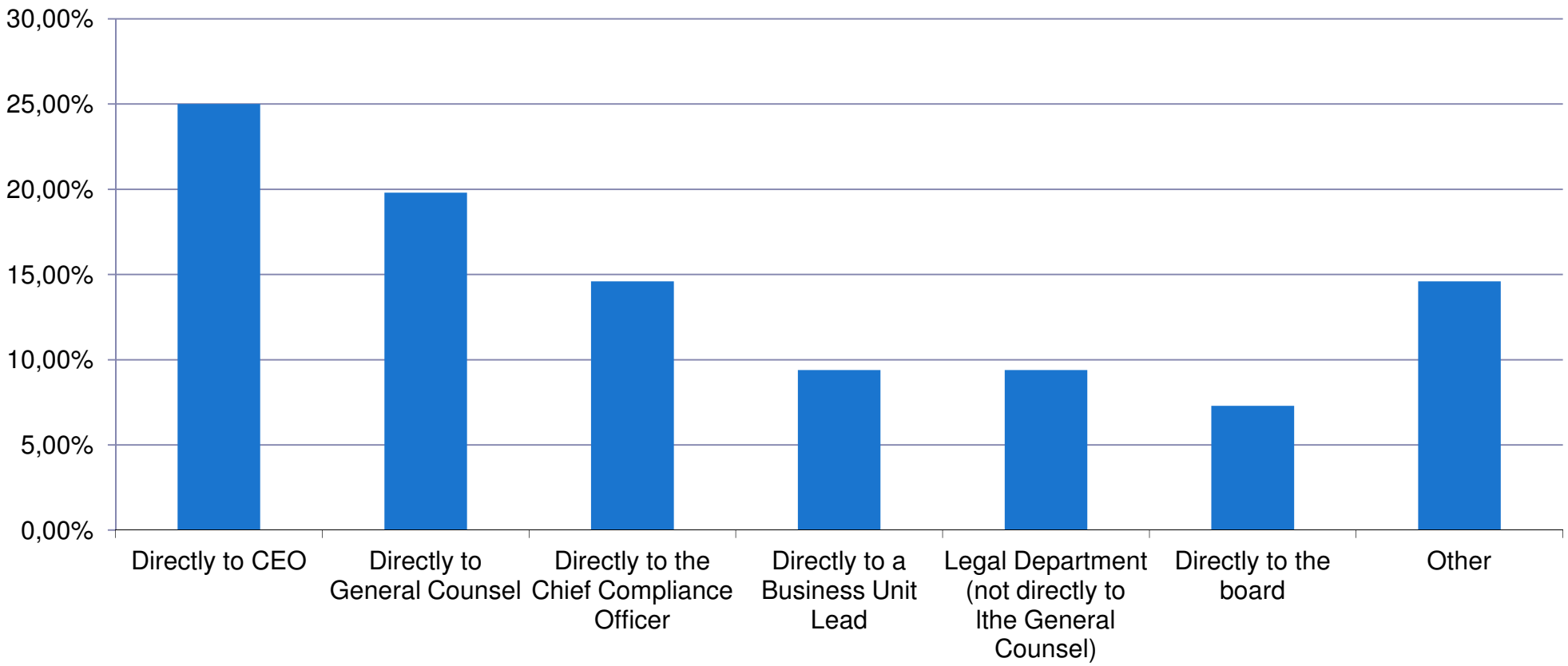
Base: All respondents (medical device and pharmaceutical organizations, 102)

Source: Clifford Chance Global Compliance Benchmarking Survey 2013

Reporting lines continue to run to legal

- Regulators and other healthcare organizations, including the Office of Inspector General of the U.S. Department of Health and Human Services (OIG), caution about the risks of structuring an organization's compliance functions as subordinate to the General Counsel function.
- The majority of Chief Compliance Officers report directly to a Chief Executive Officer or Board of Directors.
- But approximately 30% still report directly to the General Counsel or Legal Department.

Q: To whom does the individual with responsibility for health care compliance (e.g., Chief Compliance Officer) in your company report?



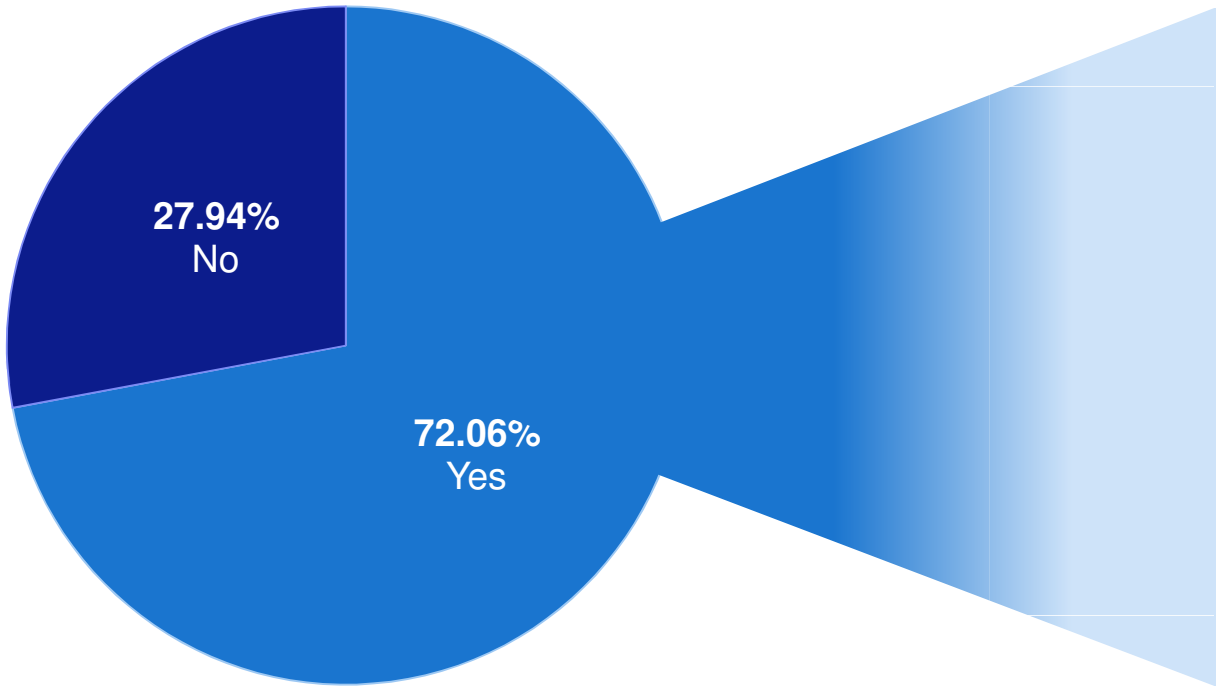
Base: All respondents (medical device and pharmaceutical organizations, 102)

Source: Clifford Chance Global Compliance Benchmarking Survey 2013

Compliance committees prevail among respondents

The prevalence of these committees indicates that healthcare companies are making a concerted effort to provide CCOs with the necessary support in the development, implementation, and oversight of their compliance programs.

Q: Does your company have a Compliance Committee?



72% of the companies have established a Compliance Committee, which comprises members from various departments, including compliance, legal, marketing, and medical or scientific affairs, etc.

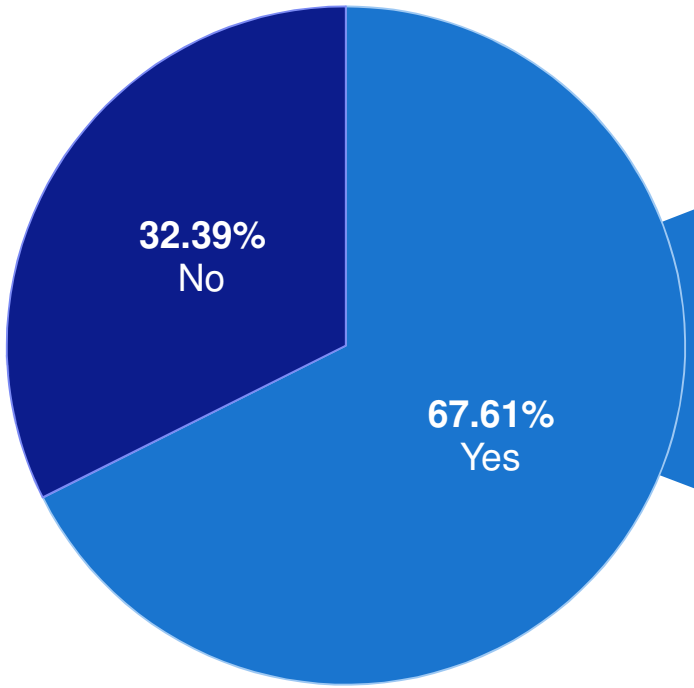
Base: All respondents (medical device and pharmaceutical organizations, 102)

Source: Clifford Chance Global Compliance Benchmarking Survey 2013

Increased use of written delegation guidelines

- Moreover, a majority of healthcare companies ensure that compliance responsibilities are delegated clearly through the use of written guidelines.
- But almost a third of respondents indicated that they do not have written guidelines.
- There is significant room for improvement within the industry as a whole.

Q: Do you have "delegation of duty" guidelines, i.e. written guidelines that allocate and define compliance responsibilities throughout your company?



Now more than 67% of the companies have written guidelines on the delegation of compliance responsibilities throughout the company.

Base: All respondents (medical device and pharmaceutical organizations, 102)

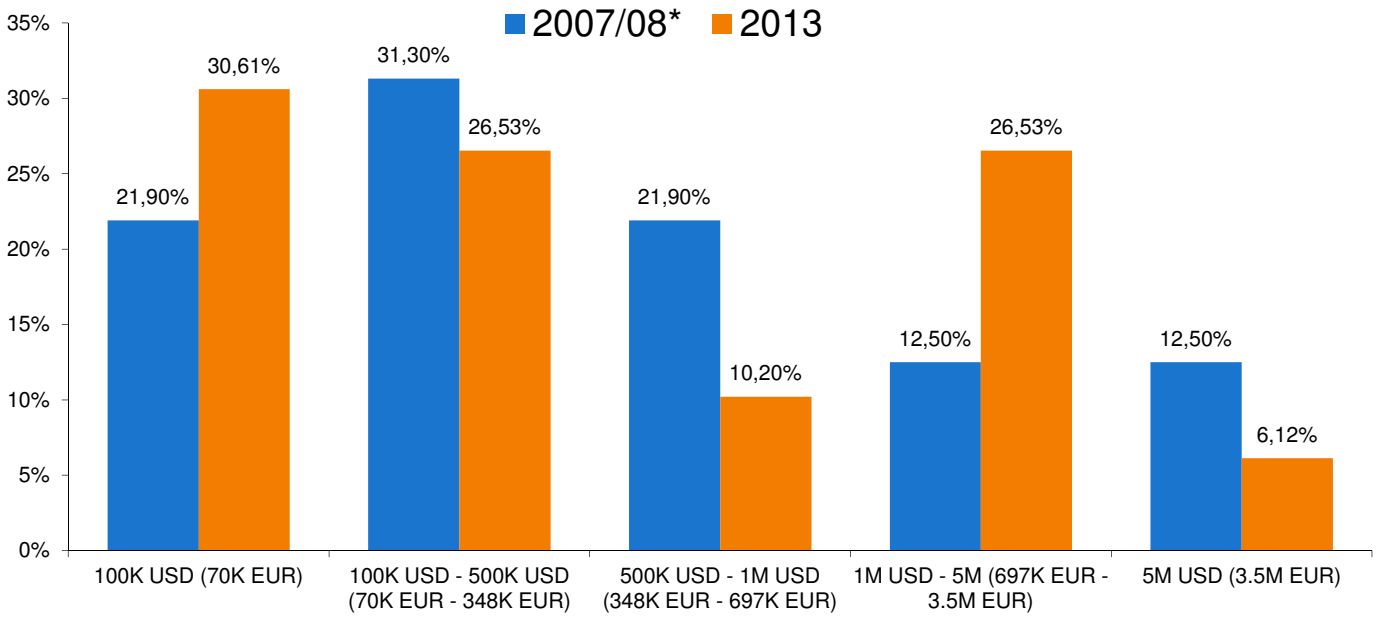
Source: Clifford Chance Global Compliance Benchmarking Survey 2013

Compliance spending is on the rise

- Companies are spending more money on compliance, which reflects both increased regulatory scrutiny as well as an increased commitment to compliance.

Q: What is the annual compliance budget for your company (excluding salaries)?

More and more companies have a higher annual compliance budget



Over **32%** of the companies now have an annual budget of $1 million compared with the 25% figure in 2007/08.

*PwC Compliance Survey 2007/08

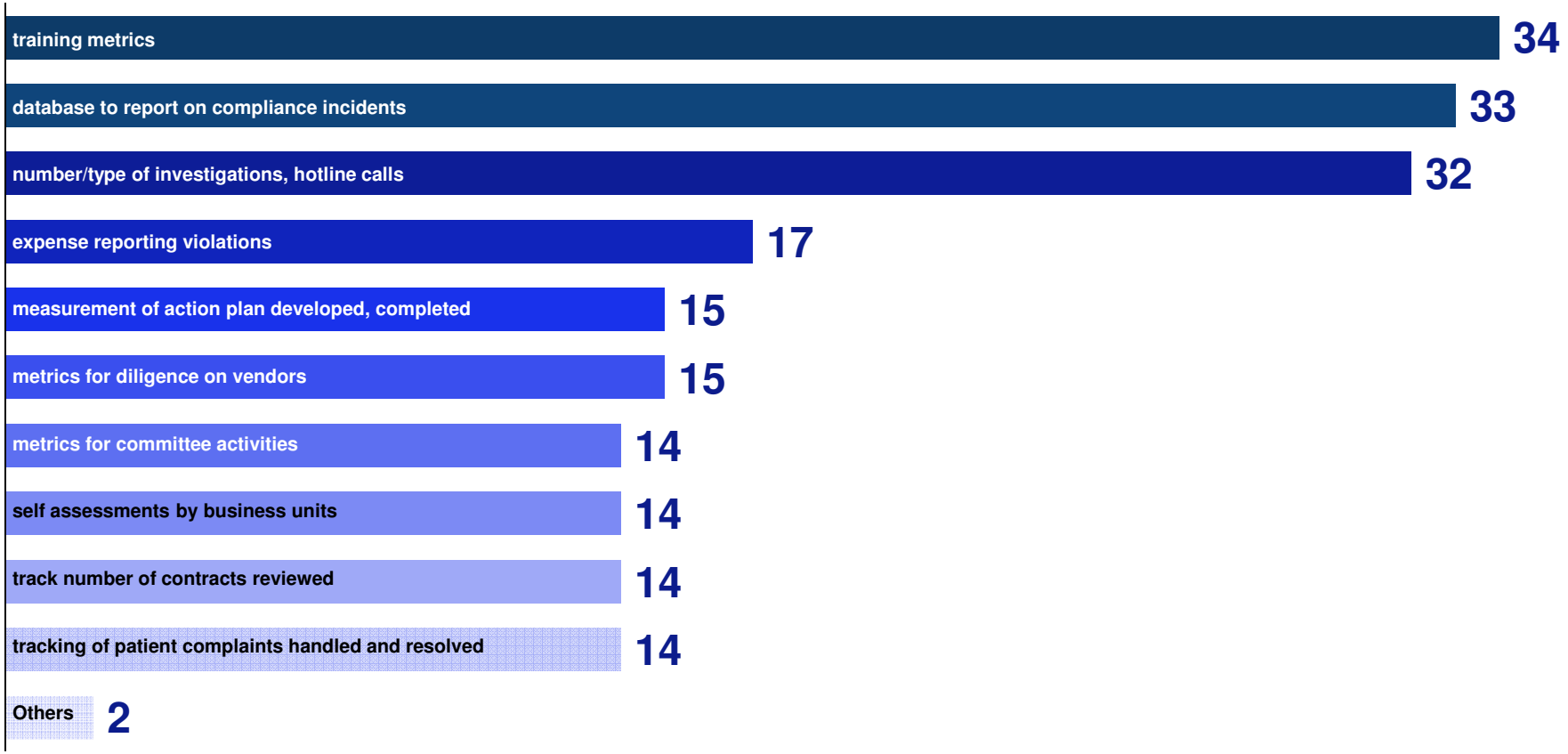
Base: All respondents (medical device and pharmaceutical organizations, 102)

Most companies do not incentivize compliance

- At the same time, the majority of healthcare companies do not reward employees monetarily for performing compliance-related tasks.
- The establishment of compliance KPIs indicates that a commitment to compliance is a core part of every employee's job.

Q: Does your company have established Compliance KPI (Key Performance Indicators)?

Many companies have established Compliance Key Performance Indicators (KPIs).



Base: All respondents (medical device and pharmaceutical organizations, 102)

Source: Clifford Chance Global Compliance Benchmarking Survey 2013

Q: Do any compliance-related Key Performance Indicators (KPIs) trigger bonus payments?

However, only 11% reward compliant behaviour with bonus payments.

Response	Frequency
No	**83,34%**
No KPI. Bonus are paid by judgement	5,56%
Complying with our company code of conduct (including 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%
Yes, it is a factor in determining some individual's bonuses	5,56%

Base: All respondents (medical device and pharmaceutical organizations, 102)

Source: Clifford Chance Global Compliance Benchmarking Survey 2013

Compliance polices, procedures, and practices

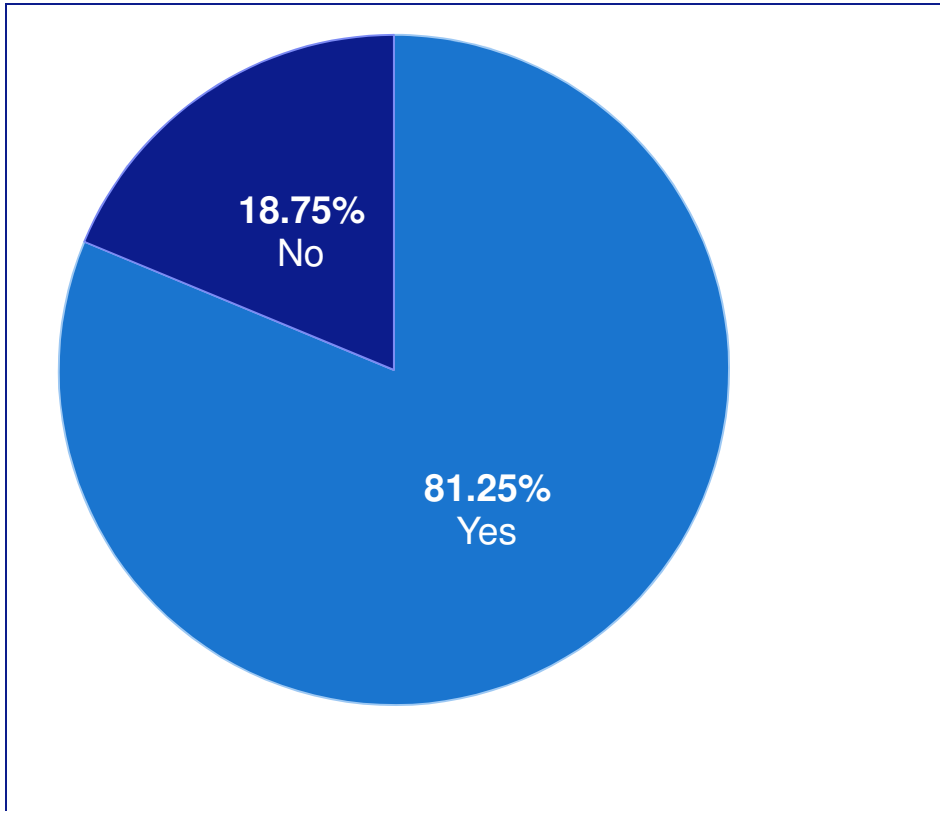
Increased use of written policies regarding HCPs

- Virtually all companies (approx. 97%) are documenting their policies, procedures, and practices regarding interactions with HCPs.
- Increasing numbers are also focusing on Fair Market Value guidelines.
- Industry-wide commitment to written policies/procedures and a increased focus on key compliance risk areas reflect an increased commitment to compliance.

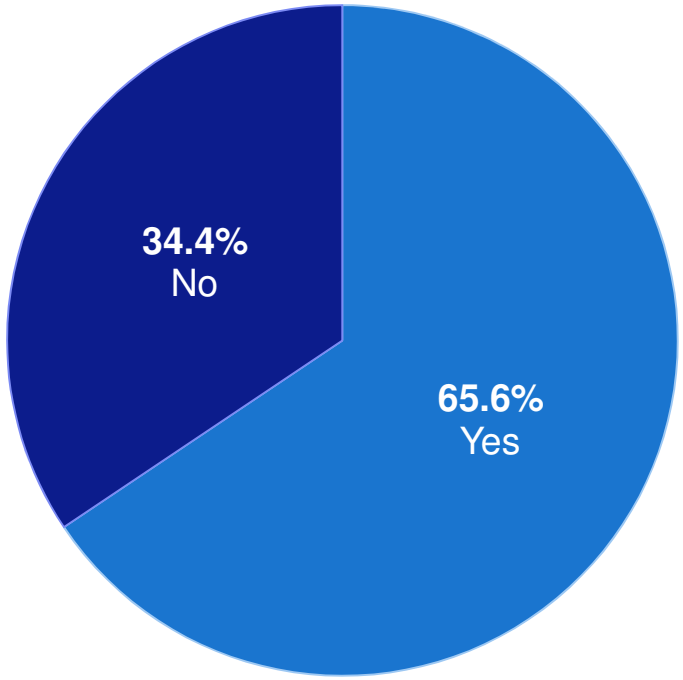
Q: Does your company have a policy regarding Fair Market Value (FMV) for services provided by healthcare professionals?

Respondents indicate an increase of 15.65% for FMV policies for services.

2013



2007/08*



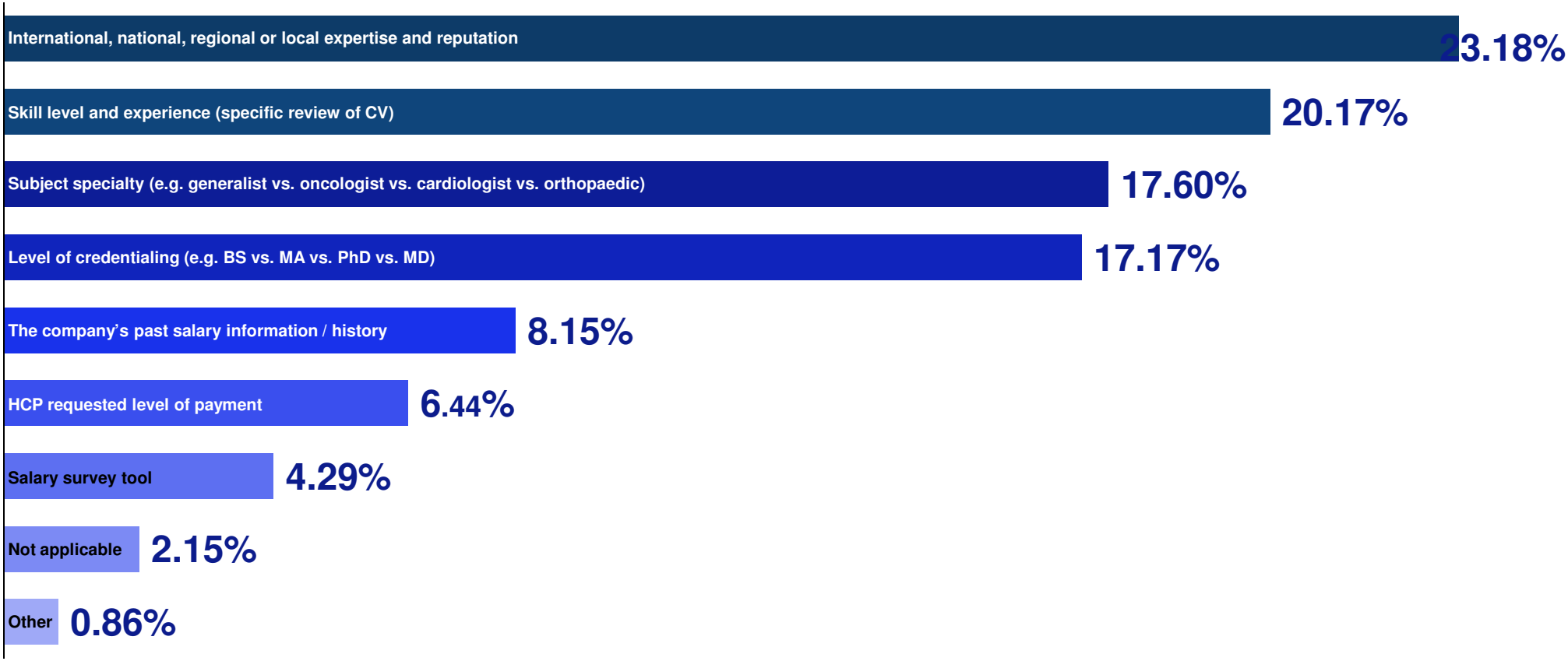
*PwC Compliance Survey 2007/08

Base: All respondents (medical device and pharmaceutical organizations, 102)

Source: Clifford Chance Global Compliance Benchmarking Survey 2013

Q: Which factors are considered in determining FMV for services?

Expertise and reputation, skill level and experience, subject specialty, and level of credentialing are the primary factors companies consider in determining FMV for HCP services

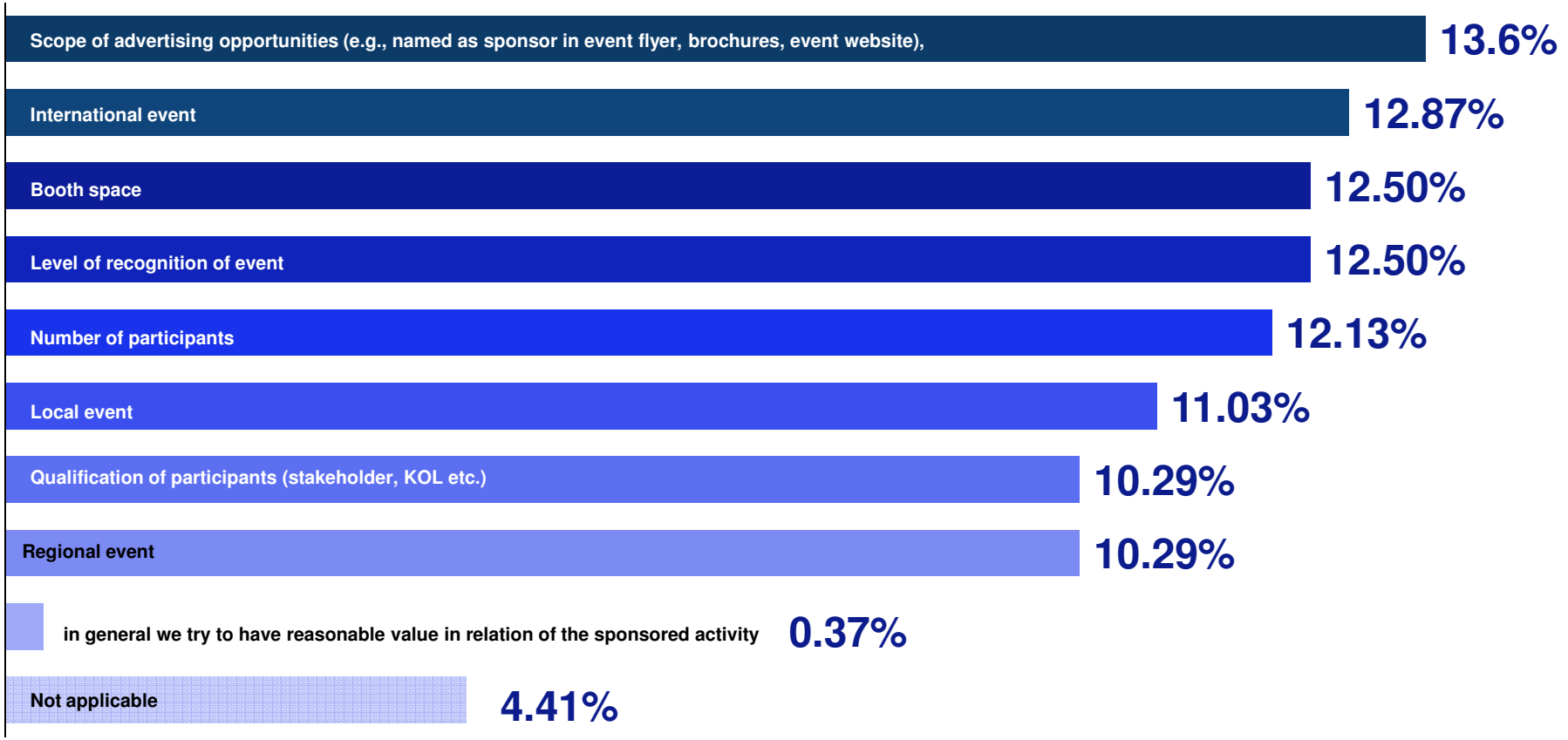


Base: All respondents (medical device and pharmaceutical organizations, 102)

Source: Clifford Chance Global Compliance Benchmarking Survey 2013

Q: Which factors are considered in determining FMV for sponsoring activities?

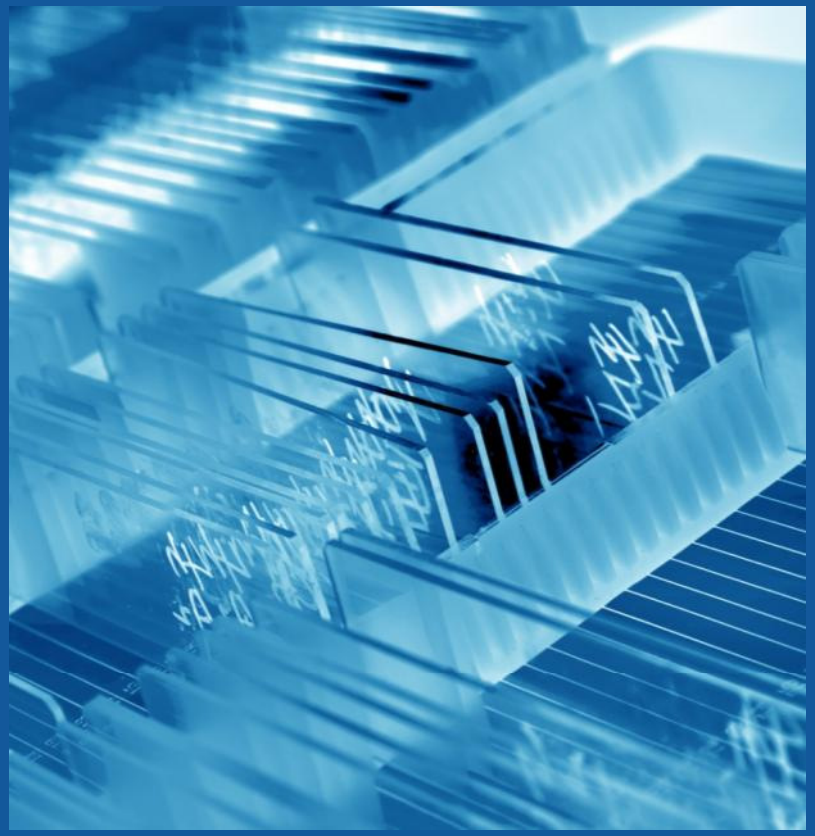
Scope of advertising, international location of event, and booth space are the primary factors considered in determining FMV for sponsoring activities



Base: All respondents (medical device and pharmaceutical organizations, 102)

Source: Clifford Chance Global Compliance Benchmarking Survey 2013

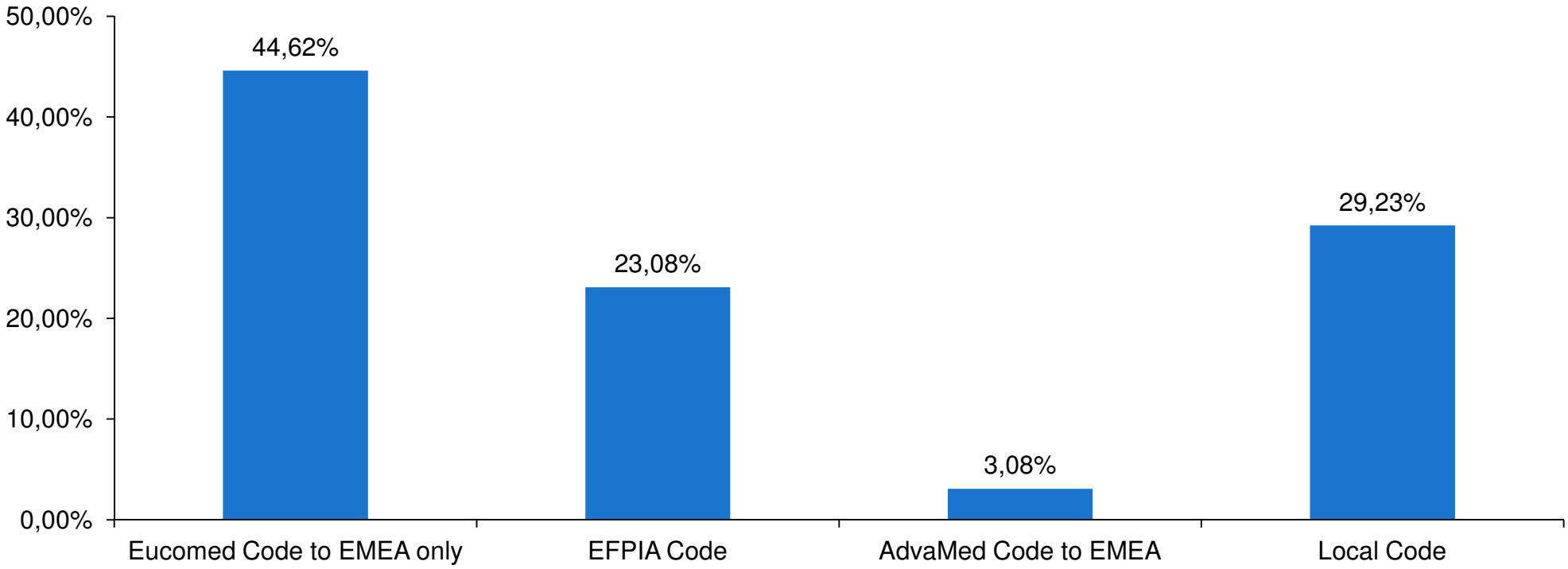
Policies based on Eucomed/EFPIA or local codes



- Even though almost half of all respondents were from U.S. multinational companies, only a little over 3% apply the AdvaMed Code to European operations.
- European policies are either based on Eucomed/EFPIA codes (approx. 70%) or on local codes (approx. 30%).

Q: Does your company apply the Eucomed Code or the AdvaMed Code or the EFPIA Code to European operations?

About 70% of the companies apply either the Eucomed Code or the EFPIA Code to European operations.



Base: All respondents (medical device and pharmaceutical organizations, 102)

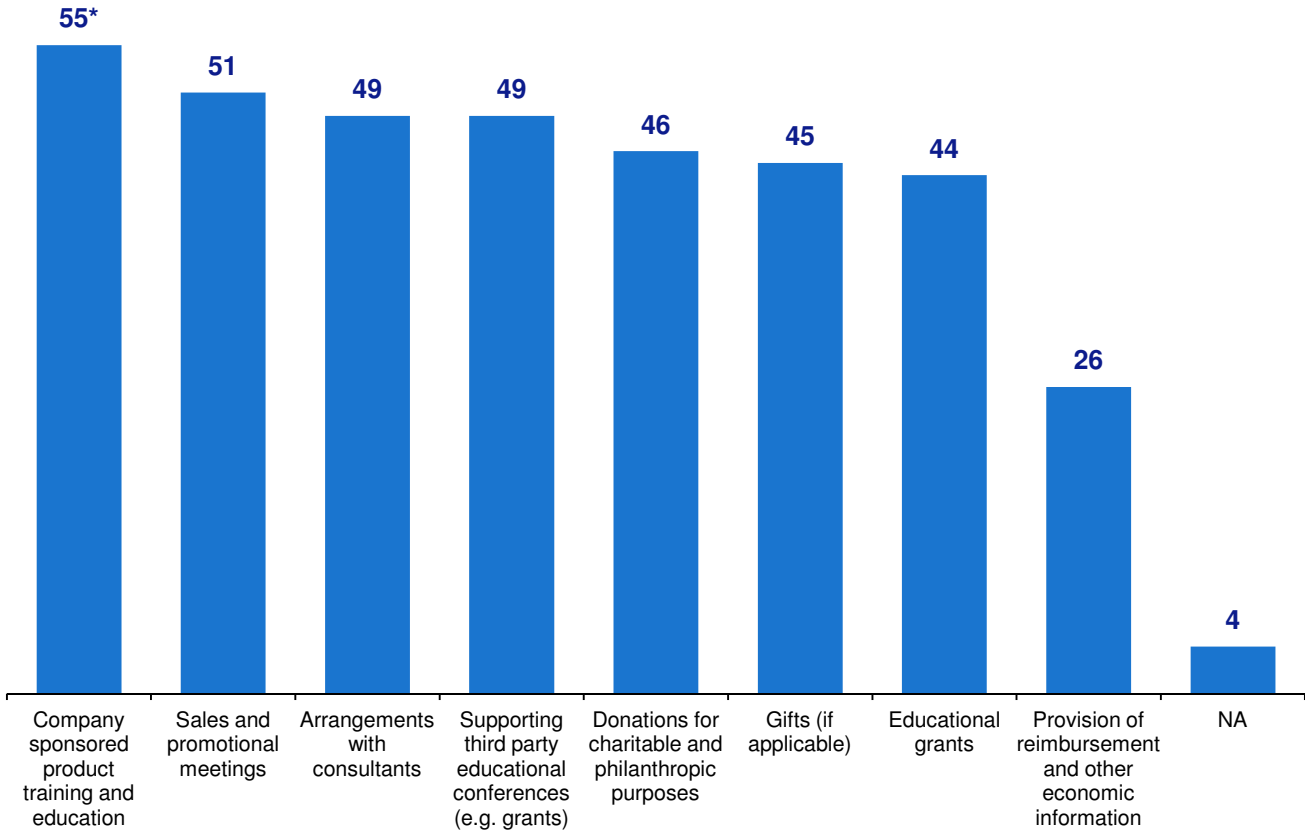
Source: Clifford Chance Global Compliance Benchmarking Survey 2013


Training

Active training methods could be more prevalent

- Compliance training appears to cover all aspects of the relevant codes equally.
- But only 60% of respondents use “active” training methods (e.g., in-person or interactive on-line training).
- The rest use “passive” methods (e.g., individual reading of policies/procedures or webcasts / web-conferences).
- Cost can be a concern, but active training methods are more effective and companies can do more to promote their use throughout the industry.

Q: If you offer compliance training, please specify which provisions you provide training on?



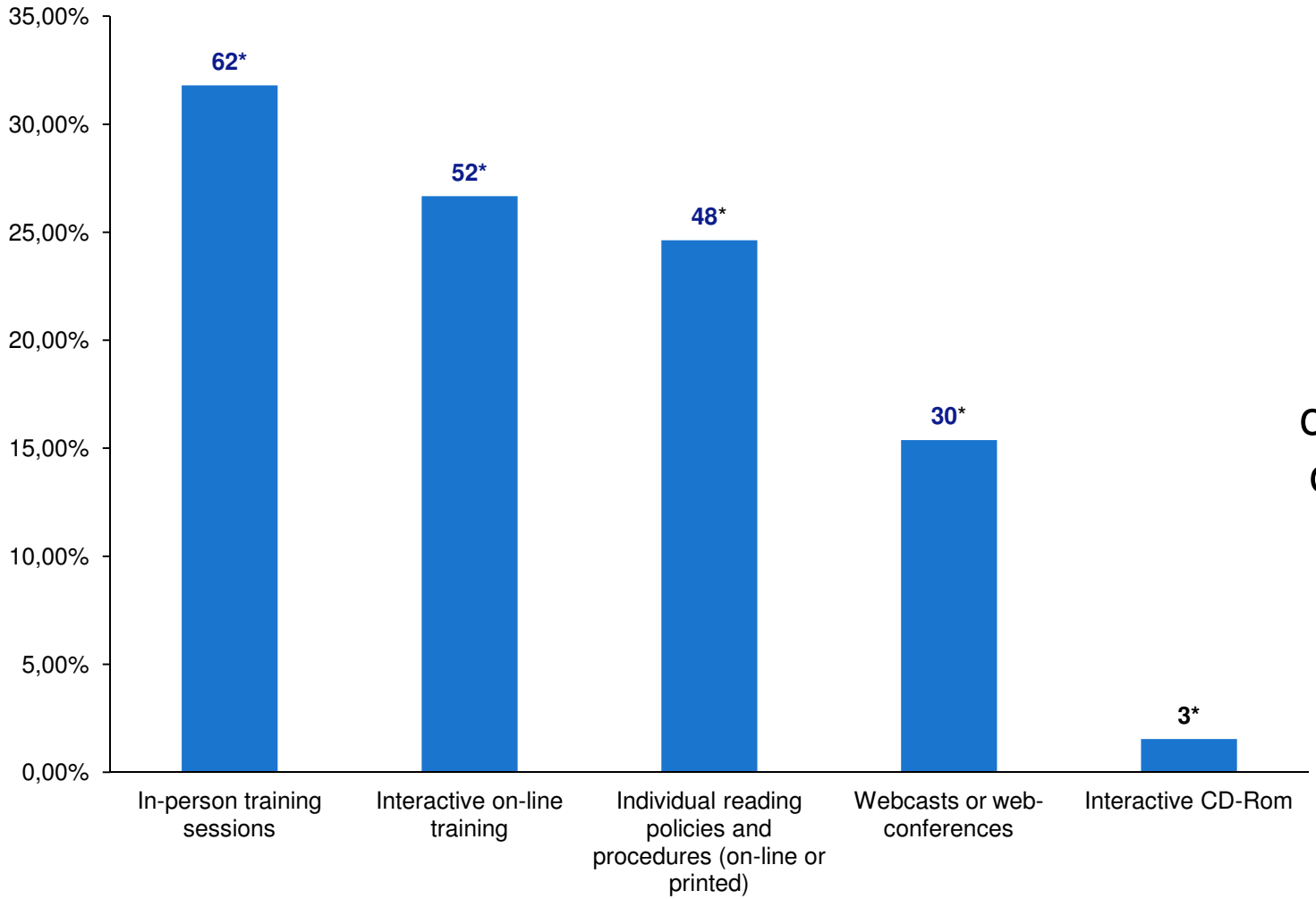
* Count

Compliance trainings include product training and education, sales and promotional meetings, arrangements with consultants, supporting third party educational conferences, donations for charitable and philanthropic purposes, gifts, educational grants, and provision of reimbursement and other economic information.

Base: All respondents (medical device and pharmaceutical organizations, 102)

Source: Clifford Chance Global Compliance Benchmarking Survey 2013

Q: What delivery methods are used for your company's compliance training?



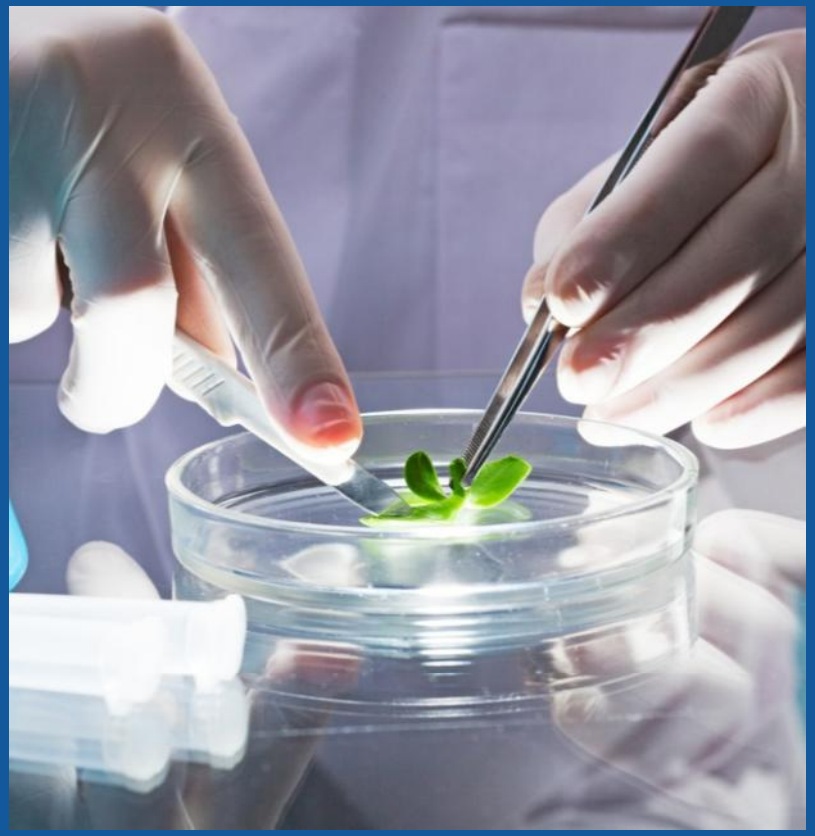
Only **60%** of companies offer either in-person or on-line interactive training sessions

* Count

Base: All respondents (medical device and pharmaceutical organizations, 102)

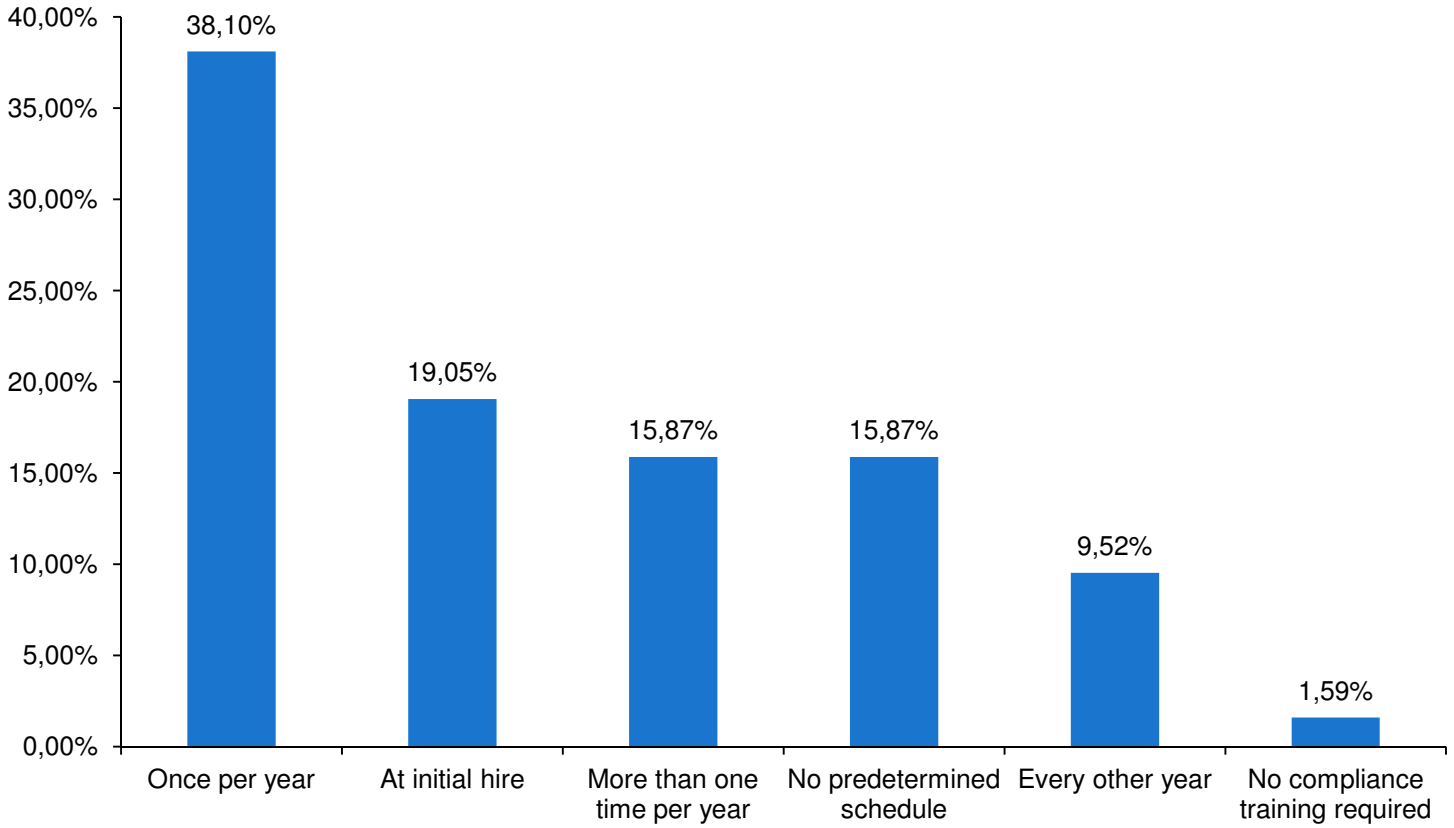
Source: Clifford Chance Global Compliance Benchmarking Survey 2013

Companies should train sales reps more frequently



- Companies are not consistent in the frequency of the training of sales representatives.
- Many factors may contribute to this inconsistency (e.g., employee turnover/retention issues; ever-changing regulations and the need for updates to the training platform; work levels of sales representatives; etc.)
- Frequent and regular training of sales representatives is a significant compliance risk mitigant – sales representatives are the first line of contact to customers.
  - Moreover, many companies rely on their sales representatives to promote their compliance with the various codes.

Q: How often are employed sales representatives required to complete compliance training?



More than 50% of the companies train their sales representatives once per year or more.

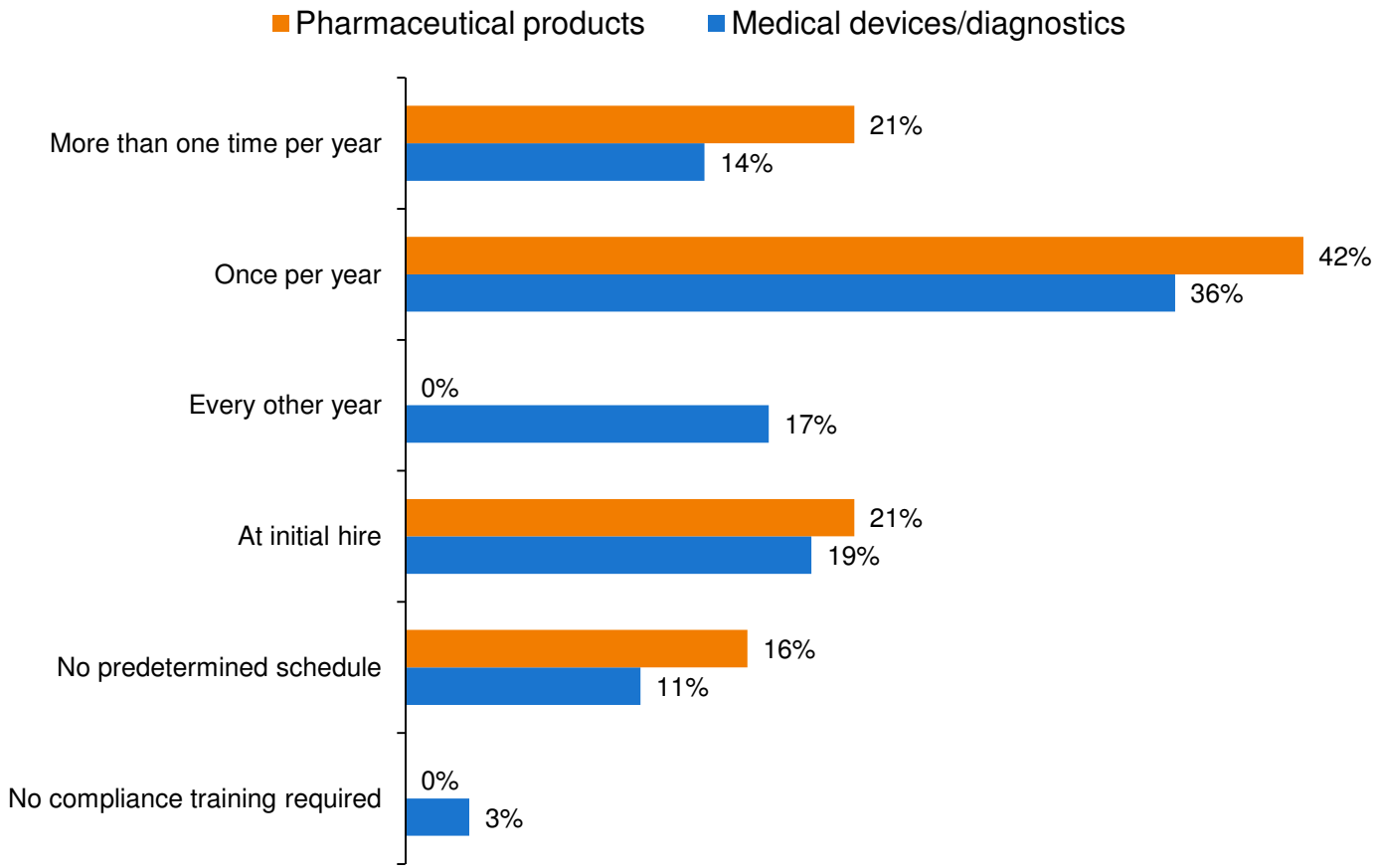
Base: All respondents (medical device and pharmaceutical organizations, 102)

Source: Clifford Chance Global Compliance Benchmarking Survey 2013

Training is more robust in the pharmaceutical sector

- The pharmaceutical sector trains its sales representatives with more frequency - 63% receiving compliance trainings at least once a year.
- In the medical device/diagnostics sector, only 50% receive compliance trainings at least once per year.

Q: How often are employed sales representatives required to complete compliance training?



Pharma reps are more frequently trained.

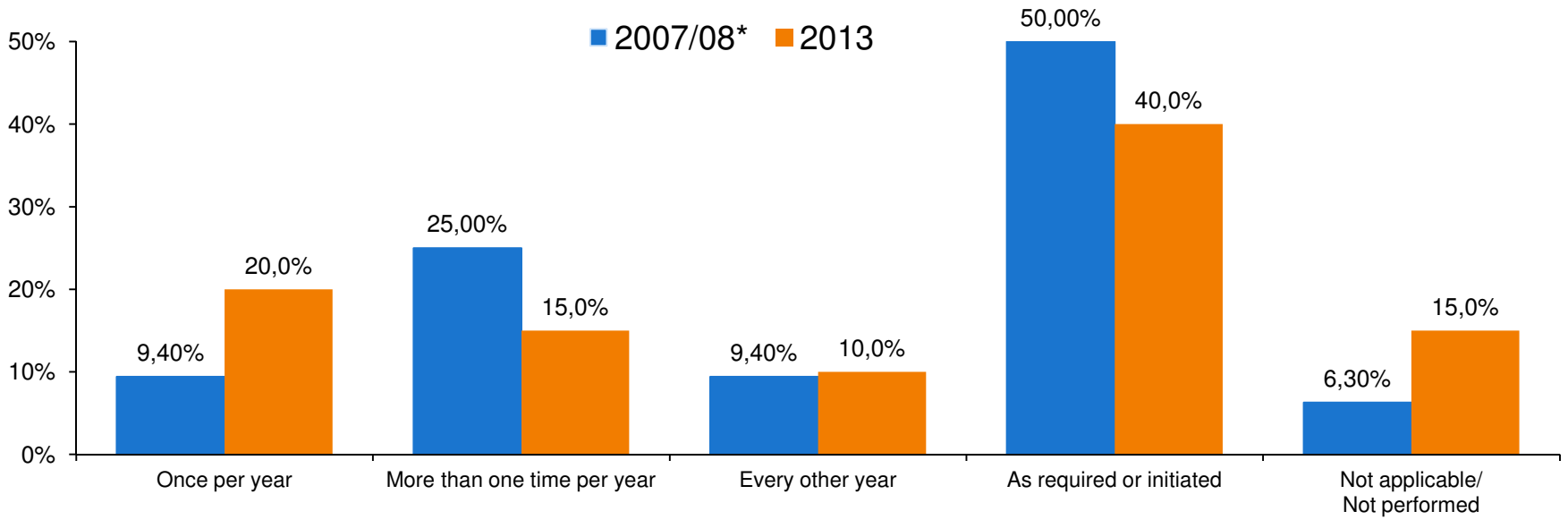
Source: Clifford Chance Global Compliance Benchmarking Survey 2013


Monitoring and auditing

Less consistency in frequency of audit practices

- Companies are not consistent in the frequency with which they conduct audits on the codes or corresponding compliance policies.
- There has been an increase in annual audits (a 10.6% increase from 2007/2008 to 2013), but a drop in more frequent auditing practices (10% decrease from 2007/2008 to 2013).

Q: How frequently are audits conducted on the AdvaMed Code, Eucomed Code or EFPIA Code or your company's corresponding compliance policies?



*PwC Compliance Survey 2007/08

Base: All respondents (medical device and pharmaceutical organizations, 102)

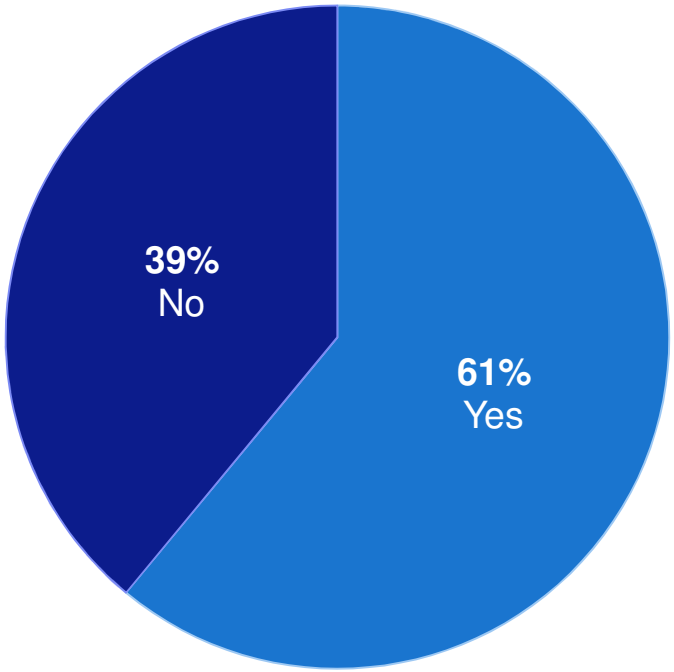
Source: Clifford Chance Global Compliance Benchmarking Survey 2013

Lack of monitoring and auditing guidelines

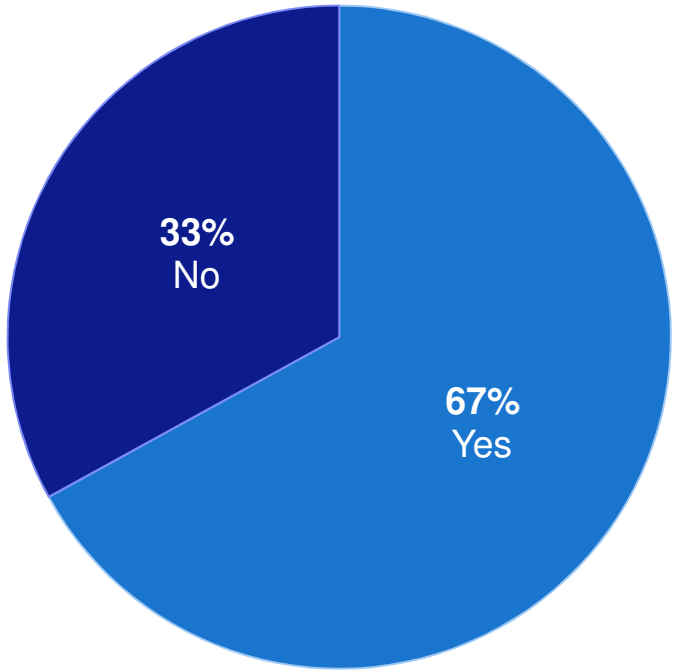
- 35% of respondents indicated that they do not have *any* monitoring and auditing guidelines.
- This large number could be reflective of the size of some of the respondents, but nevertheless represents a compliance gap that should be closed.

Q: Does your company have monitoring and auditing guidelines?

Medical devices/diagnostics



Pharmaceutical products

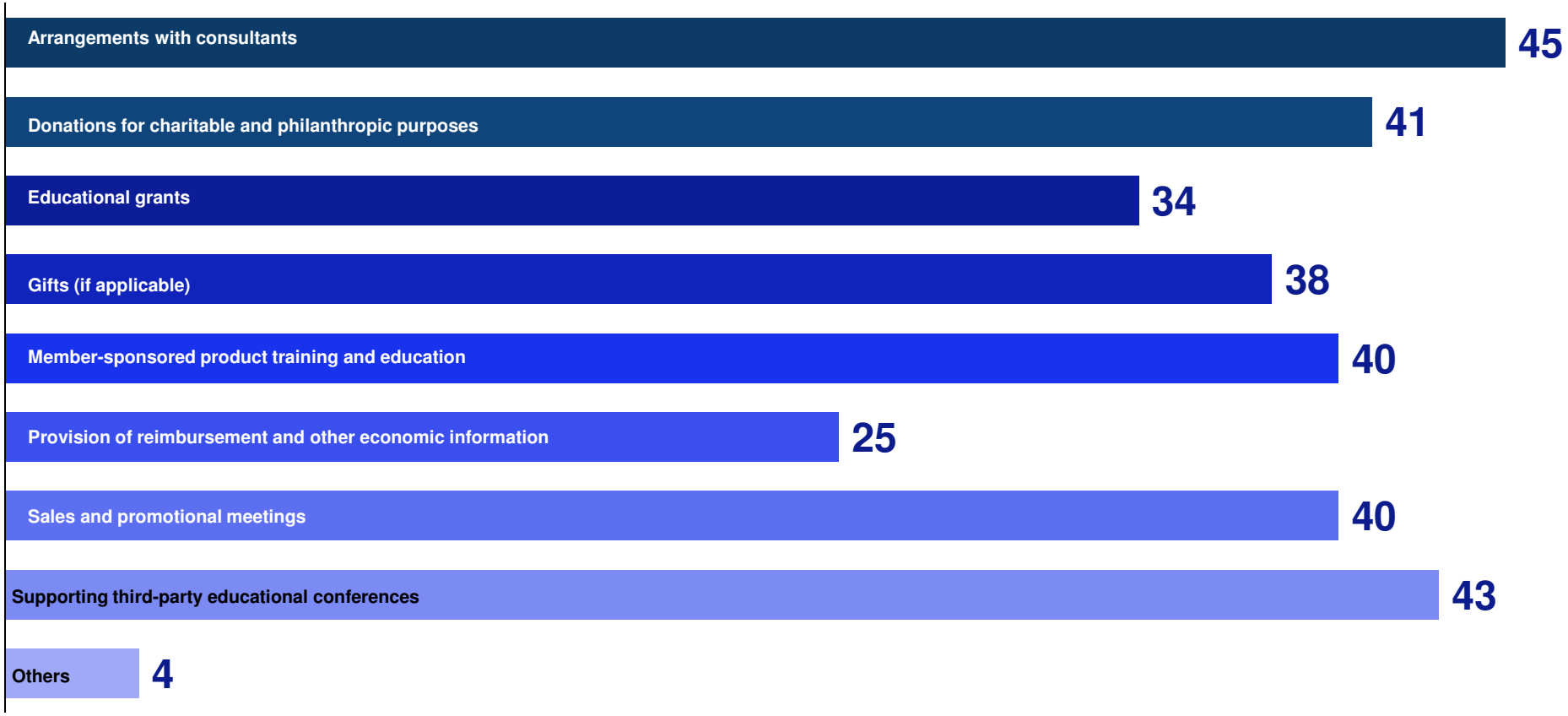


Source: Clifford Chance Global Compliance Benchmarking Survey 2013

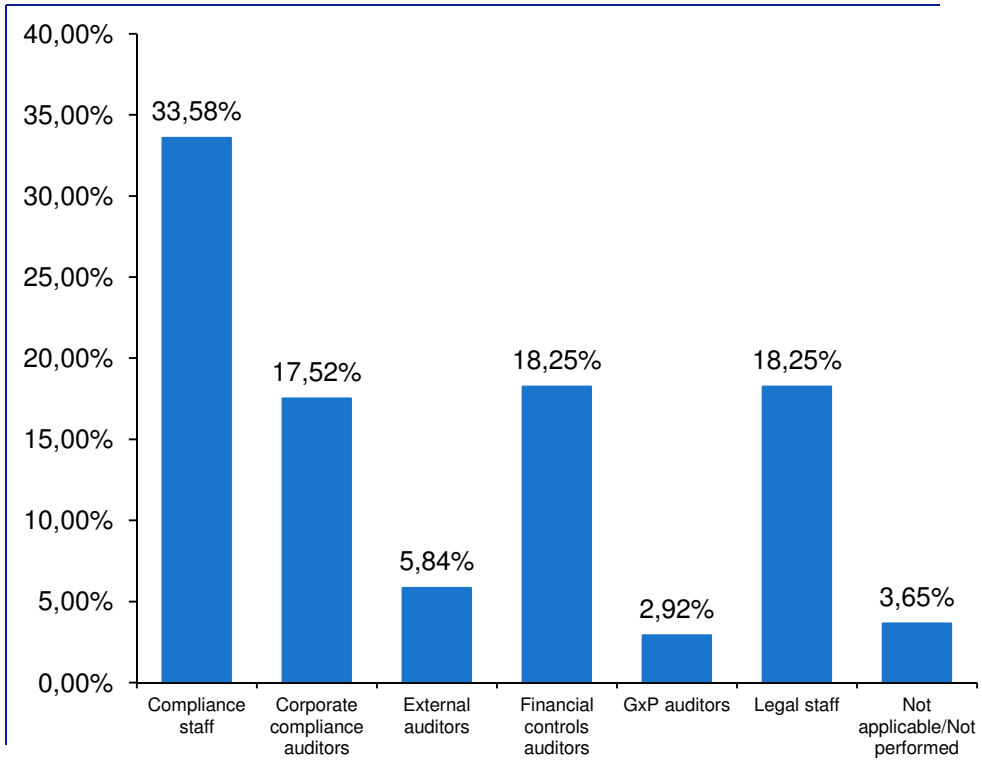
Increased audit focus on high risk areas

- Companies are targeting a wide range of higher risk activities for monitoring and auditing, which is reflective of the current regulatory/enforcement environment.
- Most monitoring and auditing is conducted by in-house specialists, with only 11% being conducted by external auditors.

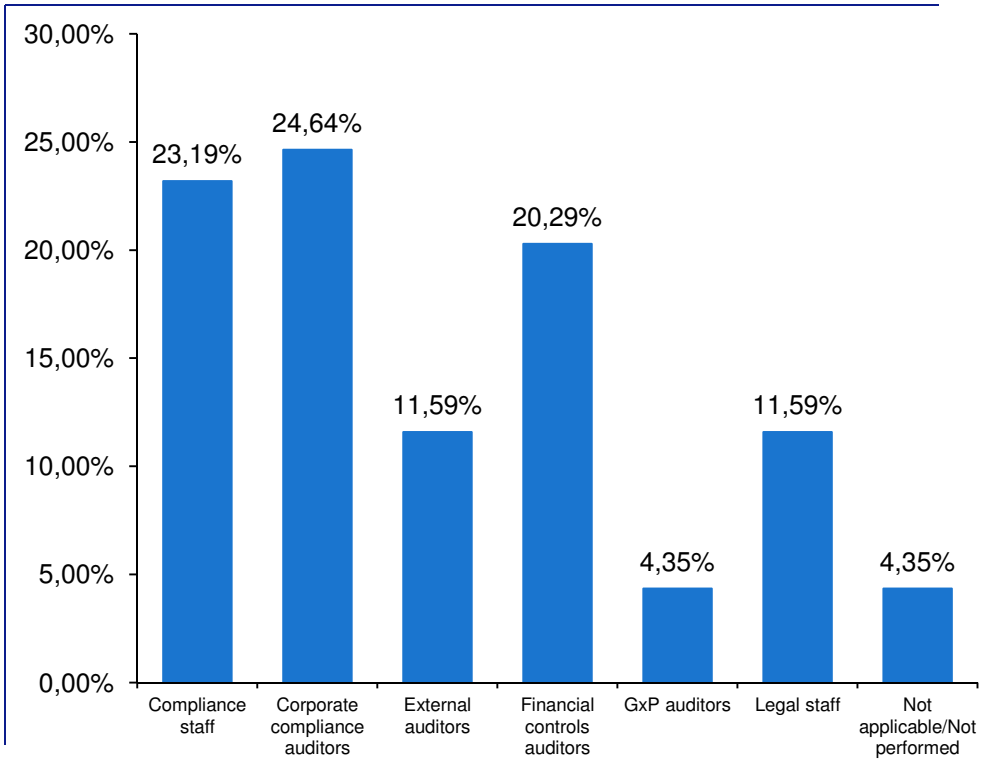
Q: Which of the following areas does your company monitor/audit?



Q: Which of the following are involved in compliance monitoring?



Which of the following are involved in compliance auditing?



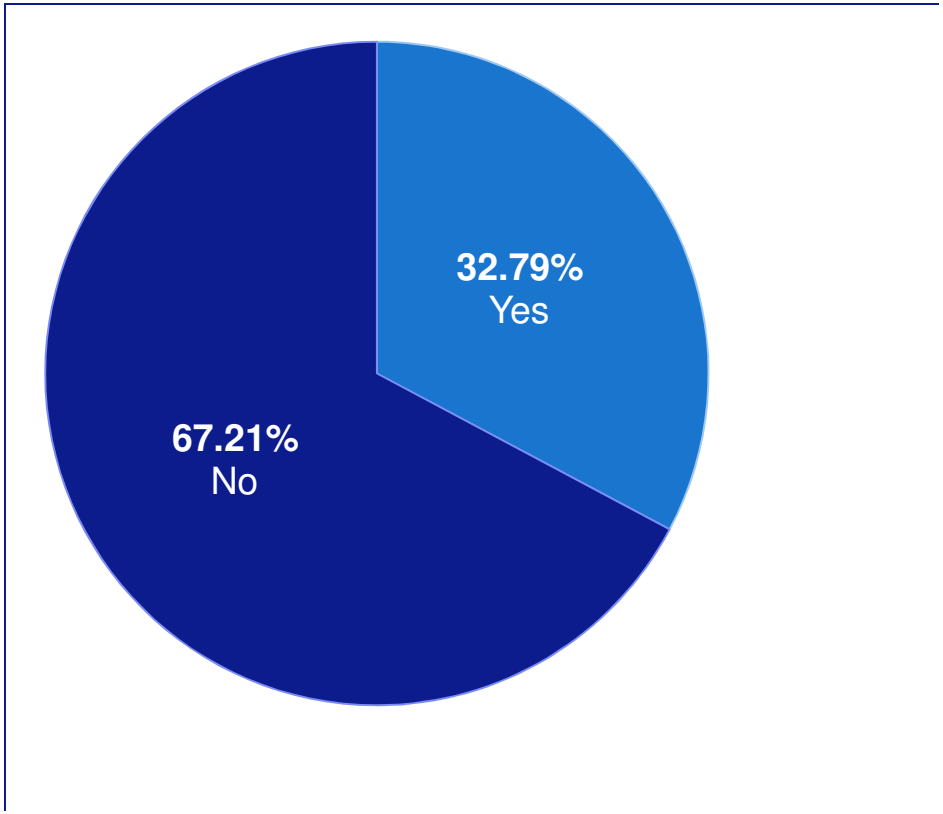
Base: All respondents (medical device and pharmaceutical organizations, 102)


Transparency

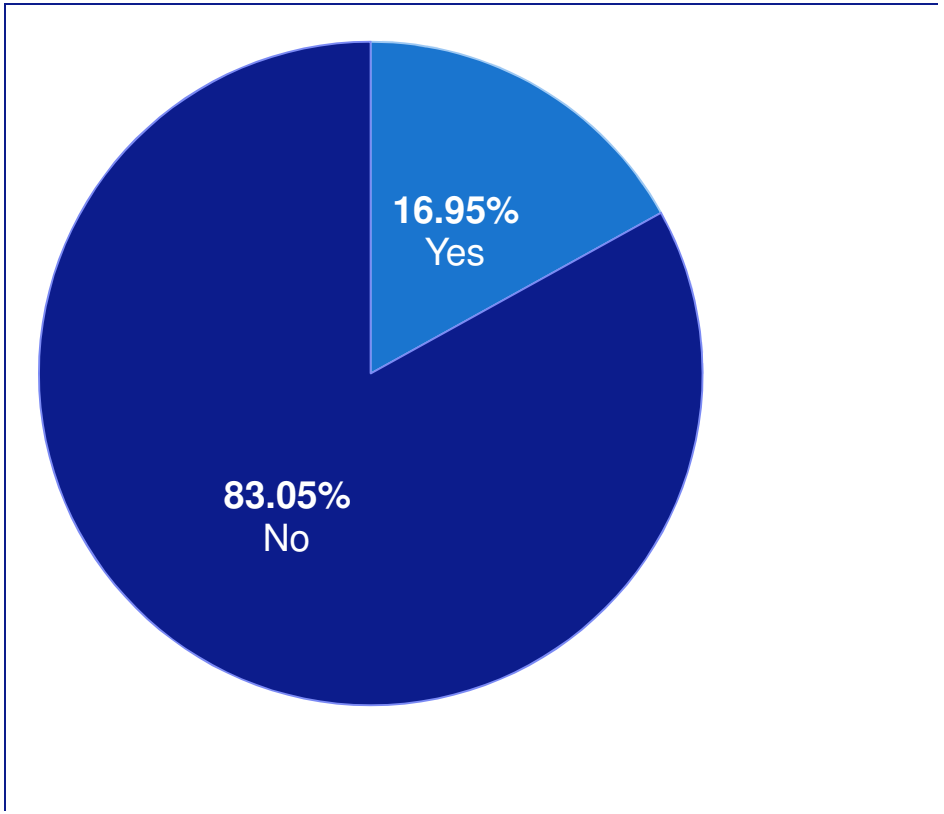
Increasing disclosure regarding HCP spending

- Although European companies lag behind their American counterparts in terms of the disclosure of information relating to spending on HCPs, the tide appears to be turning.
- Key driver: anticipation of U.S. legislation that requires disclosure of payments for U.S. healthcare professionals, French legislation and anticipation of EFPIA HCP/HCO Disclosure Code.

Q: Does your company aggregate European spending to Healthcare Professionals?



Does your company publicly disclose European spending to Healthcare Professionals?

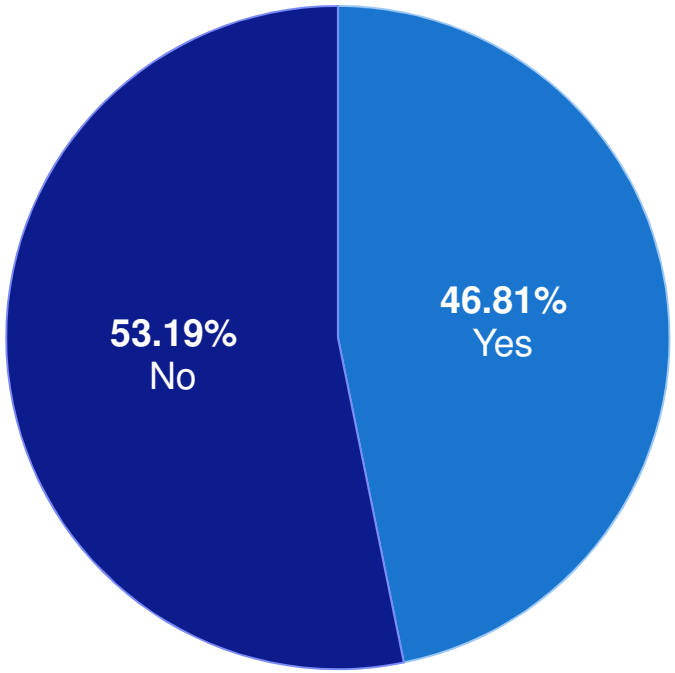


Base: All respondents (medical device and pharmaceutical organizations, 102)

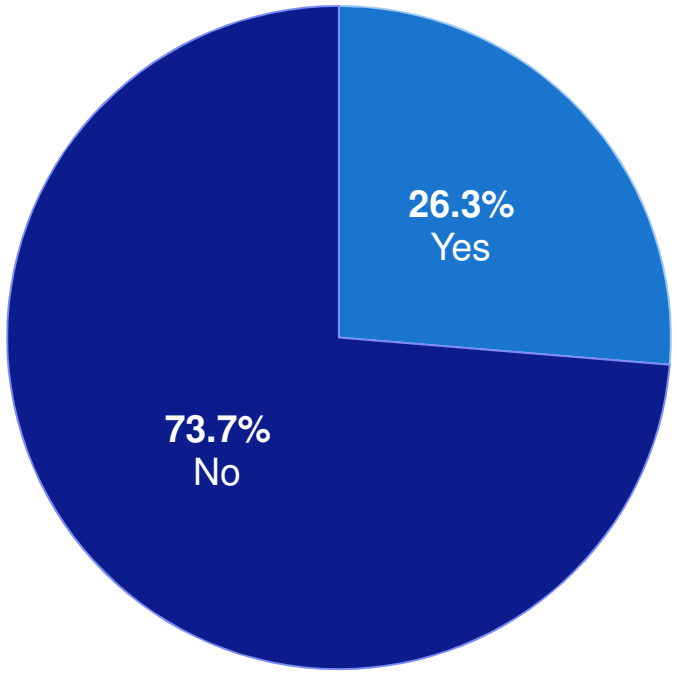
Source: Clifford Chance Global Compliance Benchmarking Survey 2013

Q: IF NO, does your company have any proactive plan to publicly disclose European financial consulting fees, charitable contributions or royalty arrangements?

2013



2007/08*



*PwC Compliance Survey 2007/08

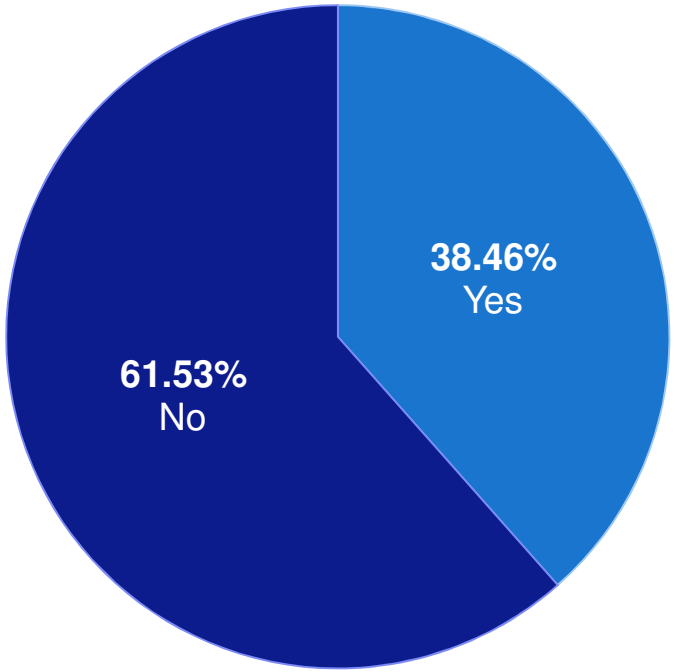
Base: All respondents (medical device and pharmaceutical organizations, 102)

Majority of Pharma has disclosure plans

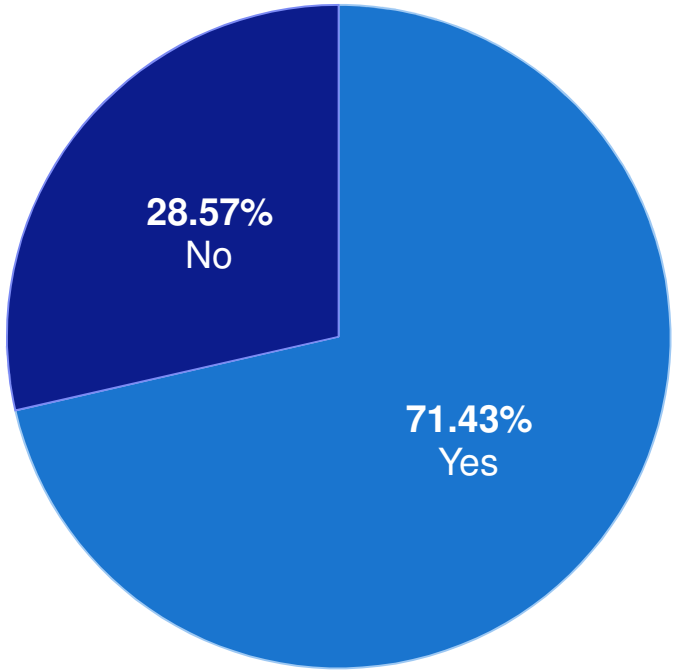
- The pharmaceutical industry is overwhelmingly more proactive than the medical device industry in taking steps to address potential disclosures of European payments.

Q: Does your company have any proactive plan to publicly disclose European financial consulting fees, charitable contributions or royalty arrangements?

Medical devices/diagnostics



Pharmaceutical products



Base: All respondents (medical device and pharmaceutical organizations, 102)

Top compliance priorities

Enforcement driving compliance priorities

- Top compliance priorities are:
  1. Distributor relationships
  2. FCPA program
  3. Due diligence programs
  4. International Ethics Code
  5. Regulatory issues / approvals
  6. Third parties (CSOs / CROs)
- Asia-Pacific and Europe top regional concerns
- The current enforcement climate has a large impact on these results – global bribery investigations (and related penalties) as well as bribery-focused due diligence exercises have been, and continue to be, a significant focus of compliance departments through the pharmaceutical and medical device industries.

Q: What are the top two (2) international priorities for your company's compliance program over the next 12 months?

Asia-Pacific and Europe are top international compliance priorities

Response	Count	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 (CSOs / CROs)	8	6.56%
Other	12	9.83%

Base: All respondents (medical device and pharmaceutical organizations, 102)

Q: Which of the following geographic areas is a top international priority for your company's compliance program over the next 12 months?

Asia-Pacific and Europe are top international compliance priorities

Response	Count	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%

Base: All respondents (medical device and pharmaceutical organizations, 102)

Survey take aways

- **Organization**
  - Reporting lines to CEO or General Counsel
  - Dominance of legal background
  - Core responsibilities of CCO: Education, policies, interactions with HCPs and government officials
  - Increasing use of Compliance Committees
  - 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
- **Policies**
  - Written Policies and Procedures are standard
  - Increased establishment of explicit fair market value policies
  - Policies are either based on Eucomed/EFPIA codes (75%) or on local codes (25%)

Survey take aways

- **Training**
  - More than 50 % are training sales representatives once per year or more, but 50 % less or without fixed intervals
  - Content of compliance training covers all aspects of the relevant codes equally
  - Only 60% provide active training
- **Monitoring and Auditing**
  - Lack of Monitoring & Auditing Guidelines (more than 1/3)
  - No real increase of audit frequency since 2007/08 survey
- **Top Compliance priorities**
  - Relationships to third parties and anti-corruption are on the top of the agenda
  - Asia-Pacific & Europe are on top of the agenda