Benchmarking Compliance for the Healthcare Industry

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

September 2013

CLIFFORD
CHANCE

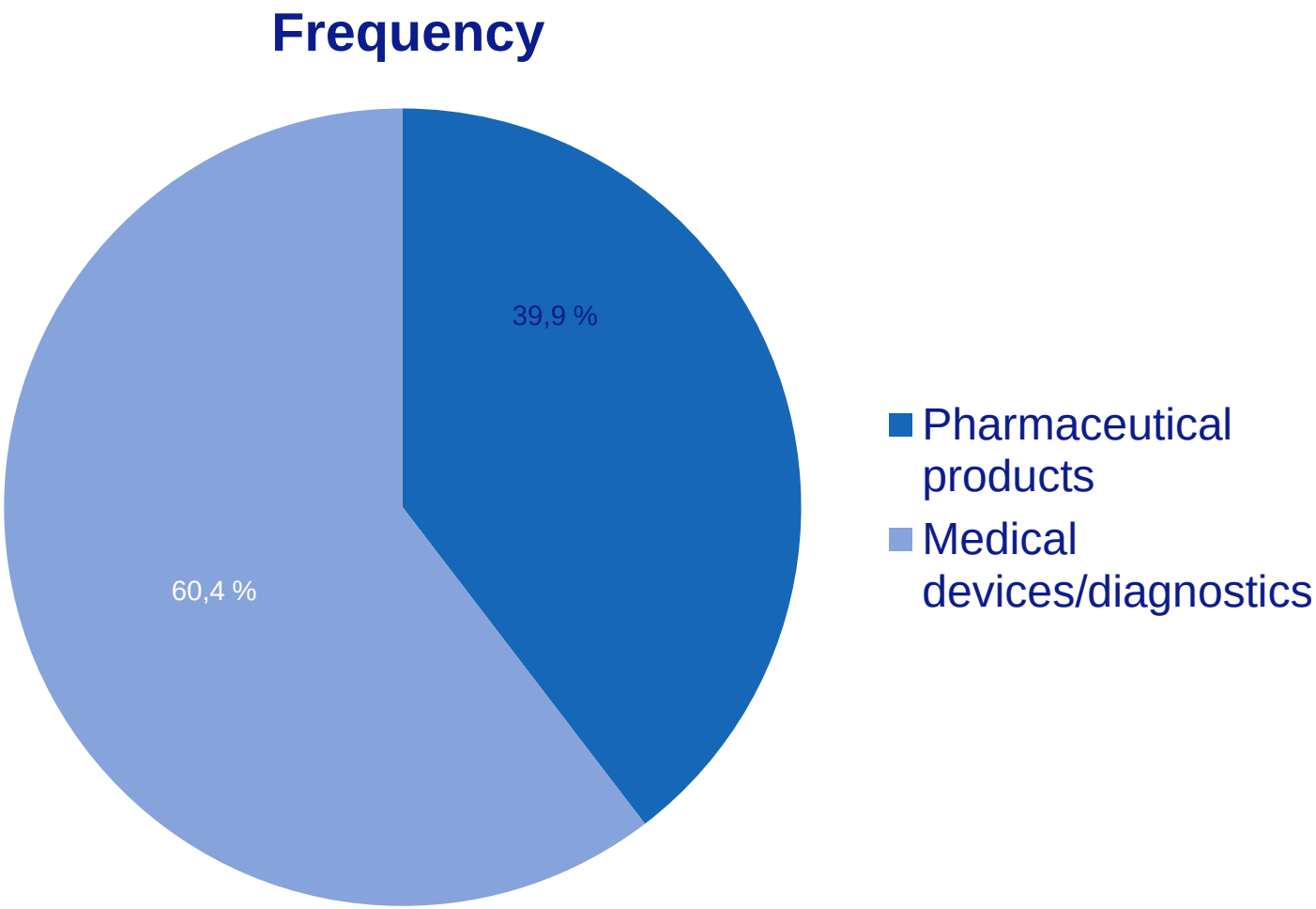
Supported by

CLIFFORD
CHANCE

Introduction

- Benchmark Survey sponsored by
  - AdvaMed
  - BVMed
  - edma
  - ETHICS
  - Eucomed
  - LEEM and
  - FSA
- Conducted in April/May 2013
- Roled 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

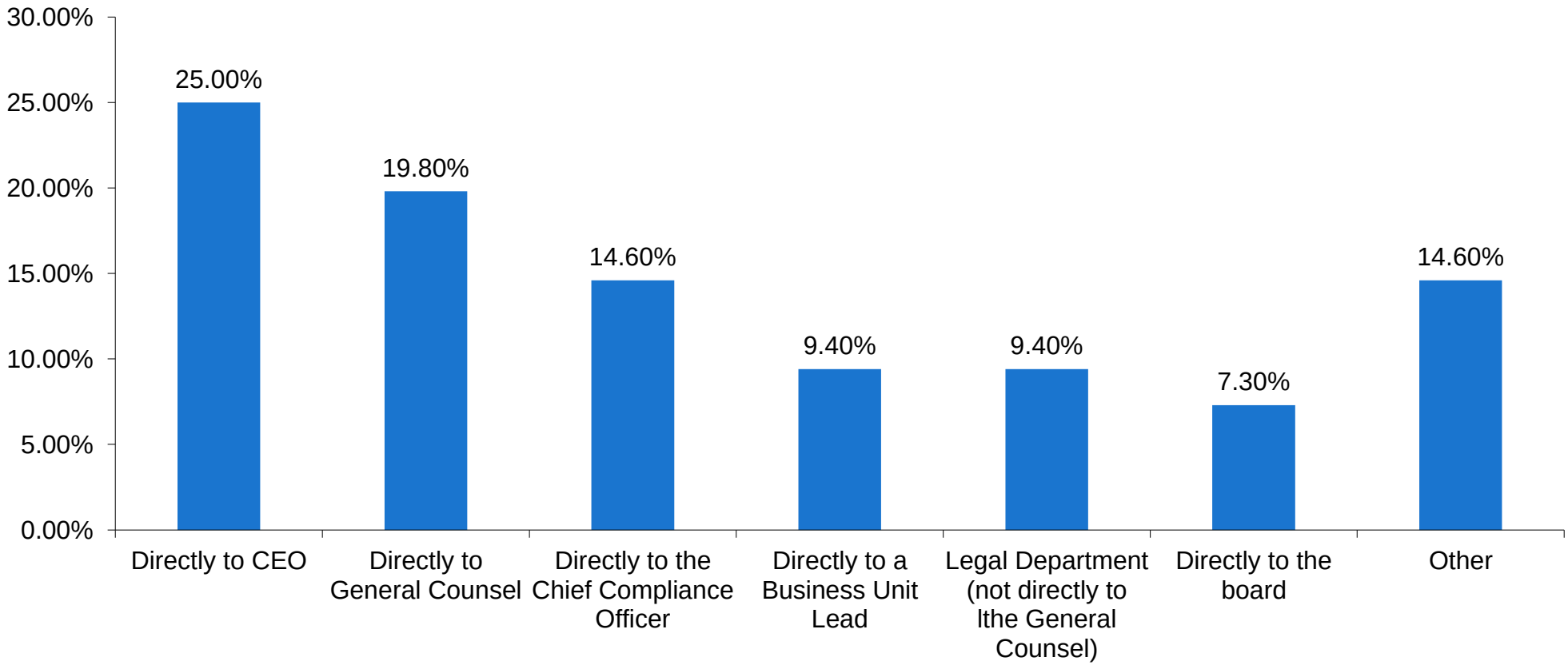
Covered product markets



- 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.
- However, even though the majority of Chief Compliance Officers report directly to a Chief Executive Officer or Board of Directors, 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?

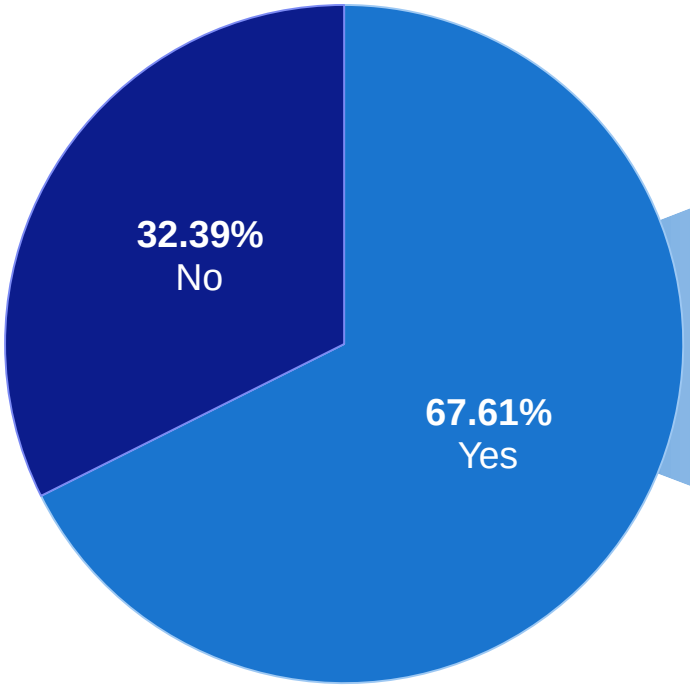
To whom do CCOs/compliance officers report regarding compliance issues?



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

Source: Clifford Chance Global Compliance Benchmarking Survey 2013

Q: Do you have a 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

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

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

Response	Count
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 handeled and resolved	14
Others	2

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% of the companies offer bonus payments to reward compliance behaviour.

Response	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%

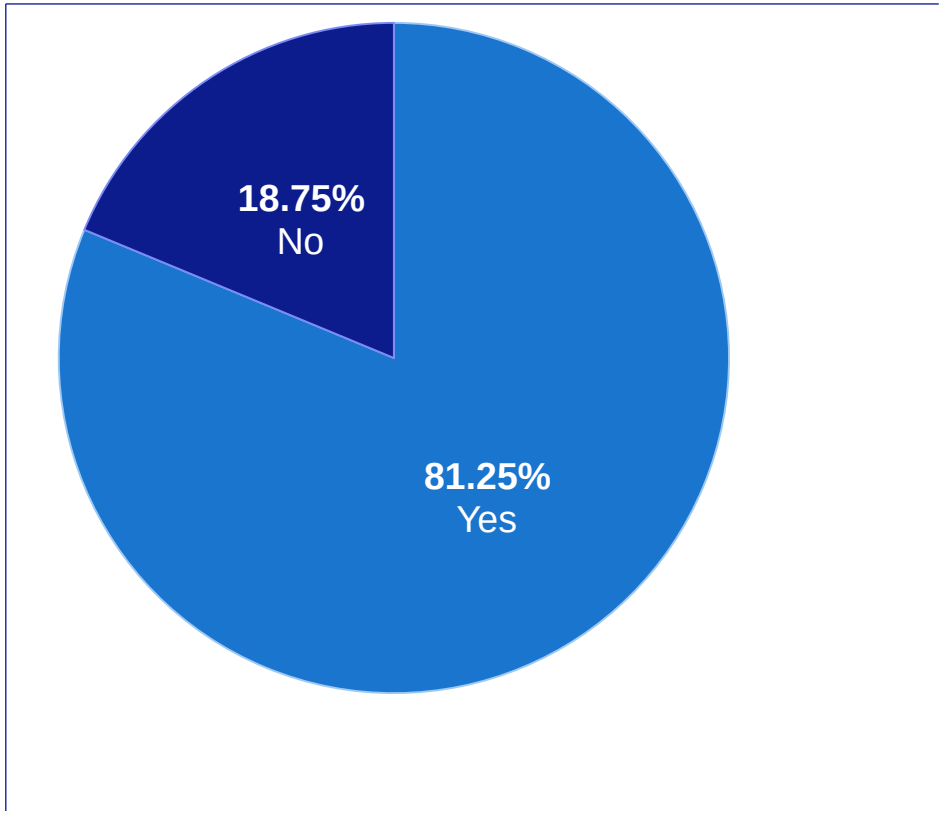
Base: All respondents (medical device and pharmaceutical organizations, 102)

Source: Clifford Chance Global Compliance Benchmarking Survey 2013

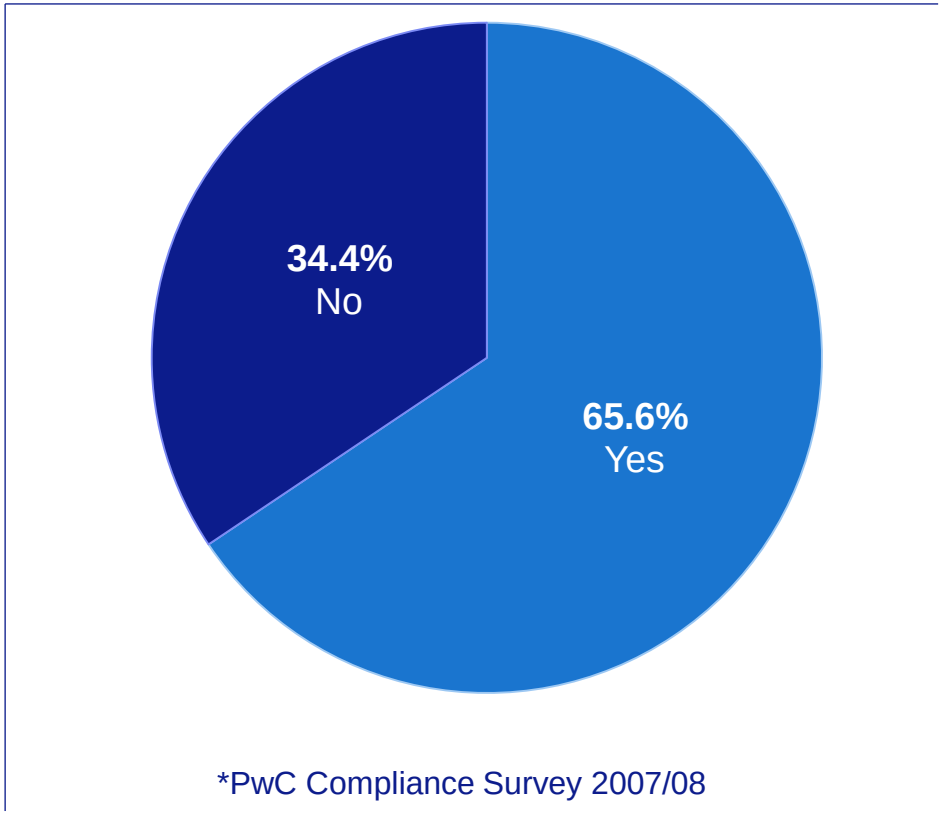
- With respect to their interactions with healthcare professionals, companies are not merely documenting their policies, procedures, and practices, but are also increasing the focus on areas of particular compliance risk.
  - Almost all respondent companies (approx. 97%) have written policies and procedures covering interactions with healthcare professionals.
  - Respondents indicate a significant increase (from 65.6% in 2007/8 to 81.25% in 2013) in companies that establish polices regarding Fair Market Value (FMV) for services provided by HCP's.
- Industry-wide commitment to written policies/procedures and a increased focus on key compliance risk areas reflects an increased commitment to compliance.

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

2013



2007/08*



*PwC Compliance Survey 2007/08

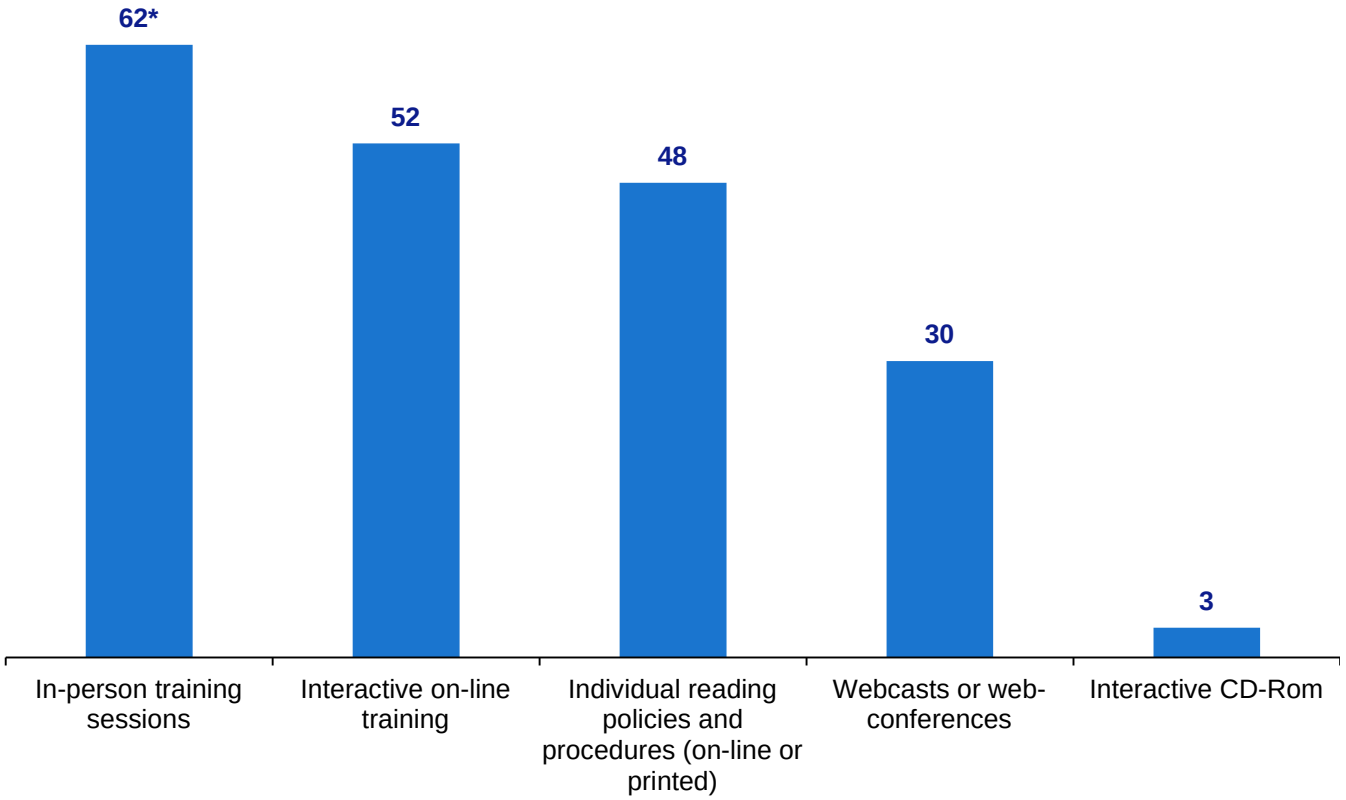
Base: All respondents (medical device and pharmaceutical organizations, 102)

Source: Clifford Chance Global Compliance Benchmarking Survey 2013

- Although compliance training appears to cover all aspects of the relevant codes equally, only 60% or 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: What delivery methods are used for your company's compliance training?

How does your company conduct the compliance trainings?



Over **half** of the companies offer either in-person or on-line interactive training sessions

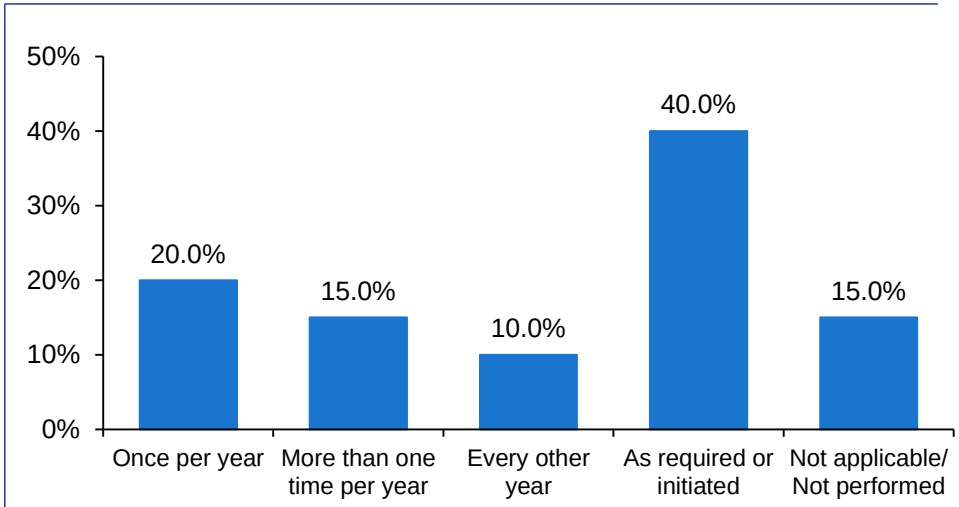
* Count

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

Source: Clifford Chance Global Compliance Benchmarking Survey 2013

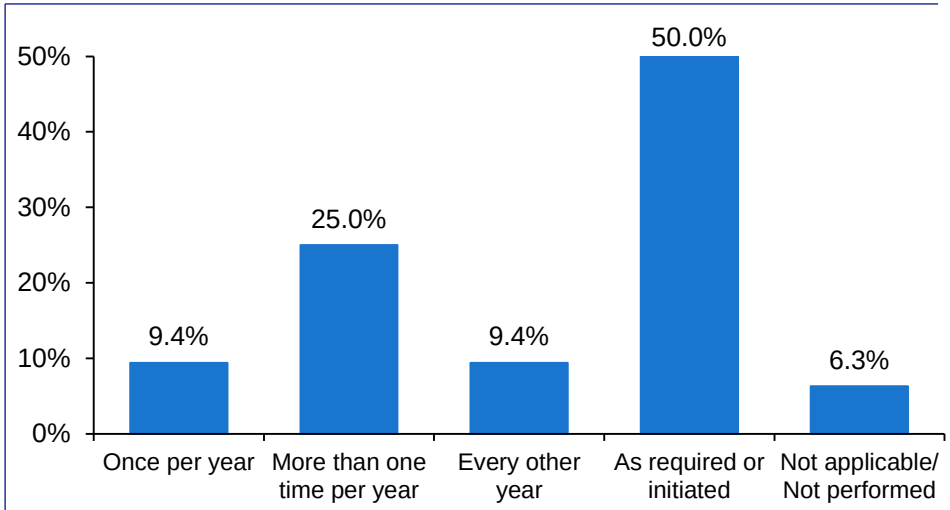
Q: How frequently are audits conducted on the AdvaMed Code, Eucomed Code or EFPIA Code or your company's corresponding compliance policies?

2013



Response	Frequency
Once per year	20.00%
More than one time per year	15.00%
Every other year	10.00%
As required or initiated	**40.00%**
Not applicable/Not performed	15.00%

2007/08*



Response	Frequency
Once per year	9.4%
More than one time per year	25.0%
Every other year	9.4%
As required or initiated	**50.0%**
Not applicable/Not performed	6.3%

*PwC Compliance Survey 2007/08

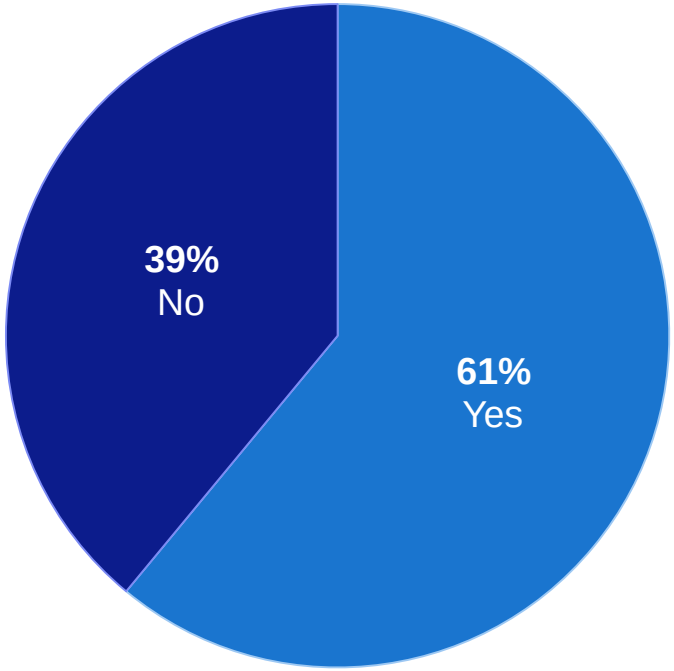
Base: All respondents (medical device and pharmaceutical organizations, 102)

Source: Clifford Chance Global Compliance Benchmarking Survey 2013

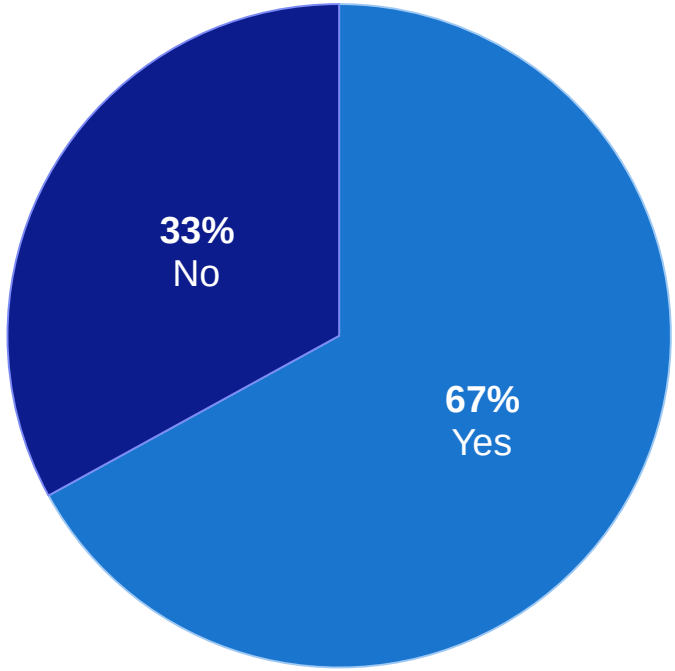
- 35% of respondents indicated that they do not have monitoring and auditing guidelines.
- This large number could be reflective of the size of some of the respondents, but nevertheless represents a compliance gap that should be closed.

Q: Does your company have monitoring and auditing guidelines?

Medical devices/diagnostics

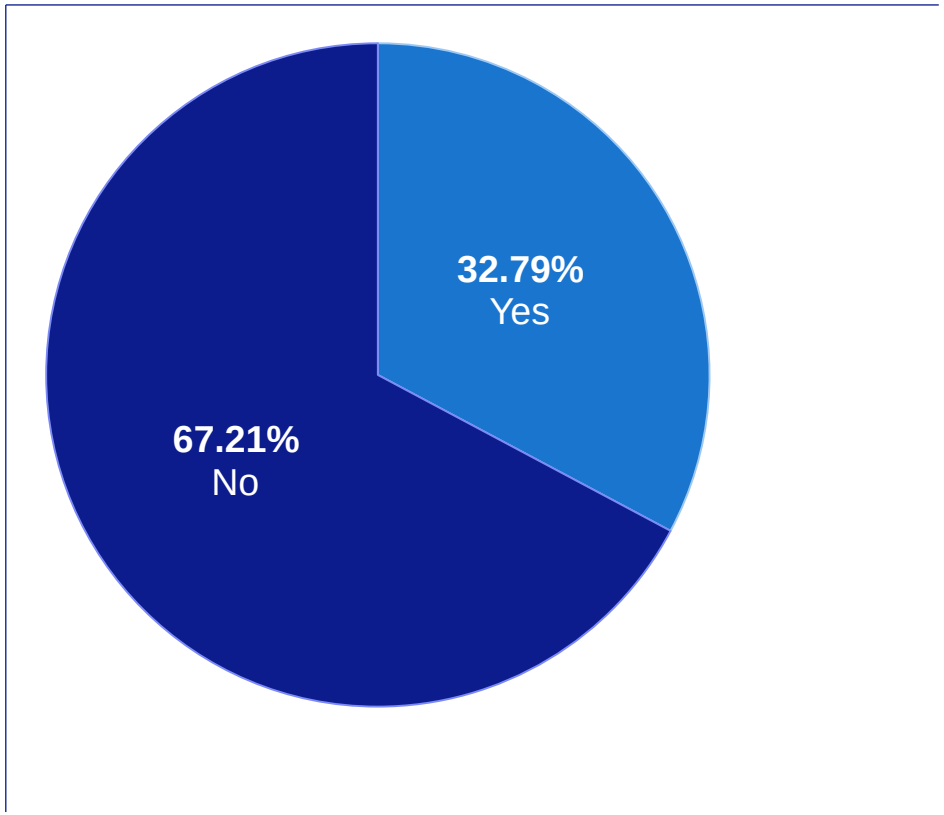


Pharmaceutical products

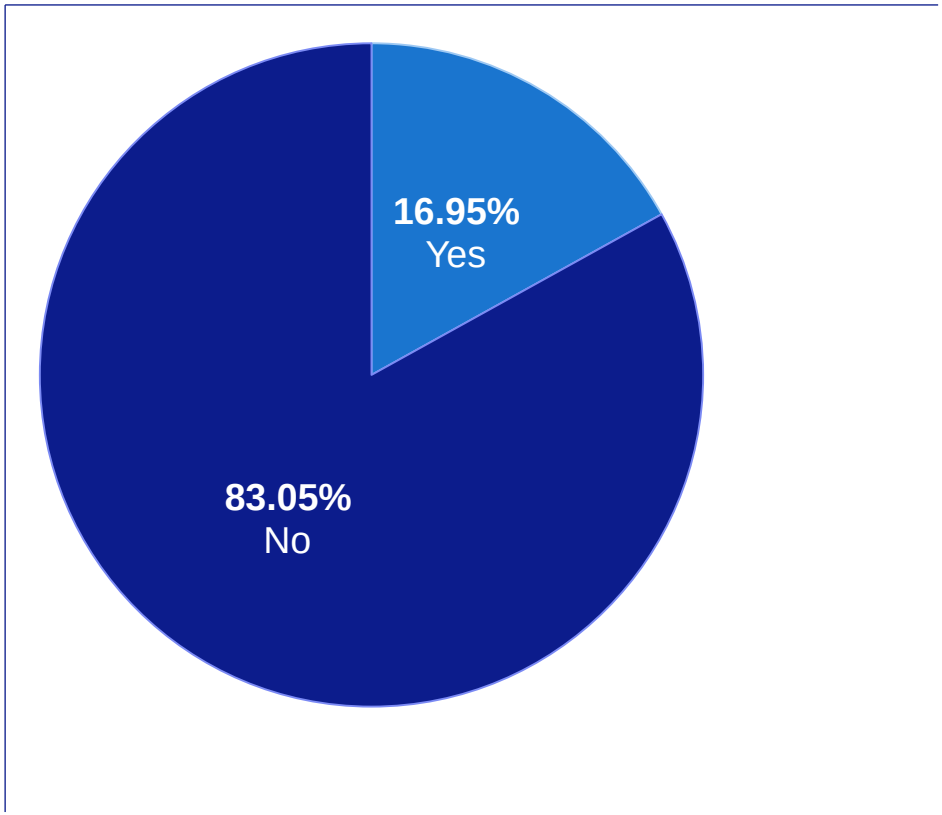


Source: Clifford Chance Global Compliance Benchmarking Survey 2013

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



Does your company publicly disclose European spending to Healthcare Professionals?

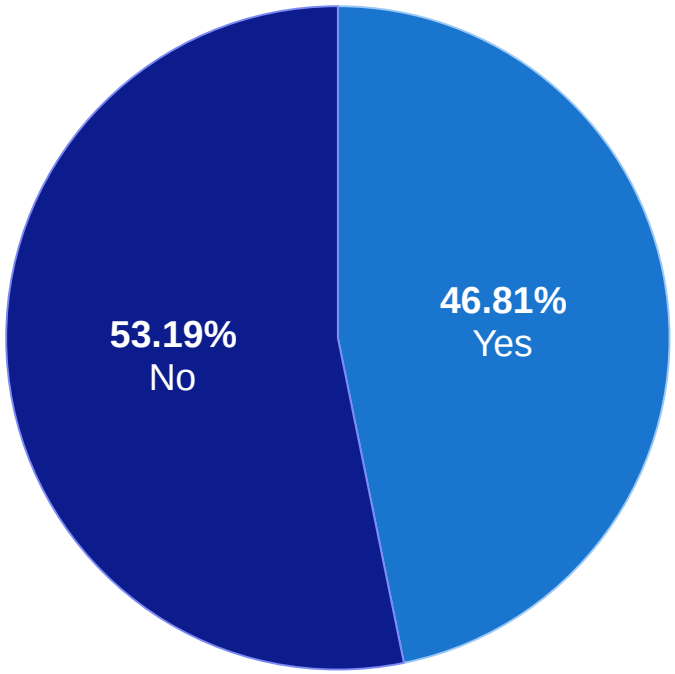


Base: All respondents (medical device and pharmaceutical organizations, 102)

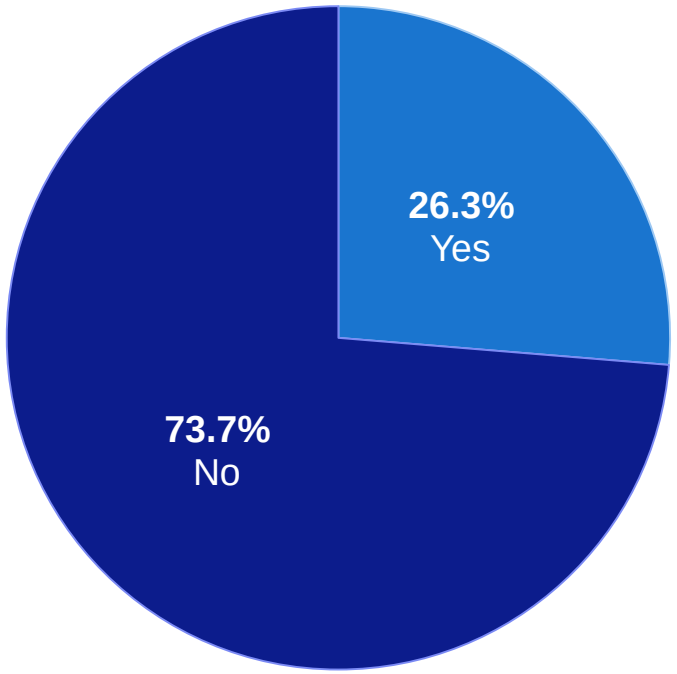
Source: Clifford Chance Global Compliance Benchmarking Survey 2013

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*

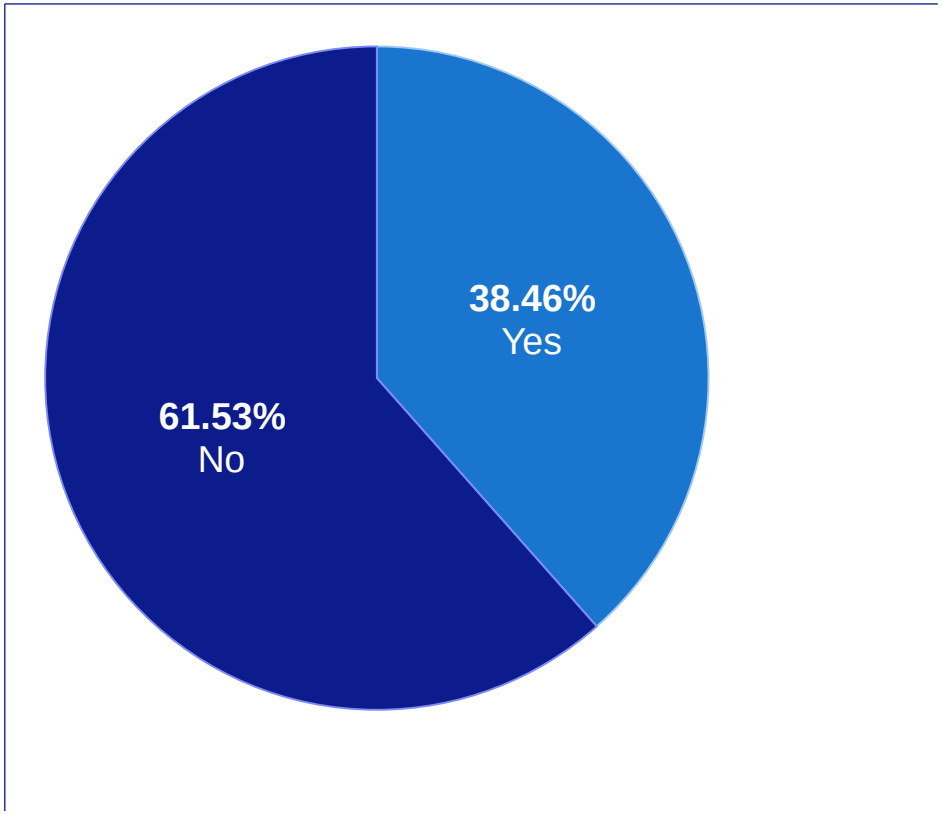


*PwC Compliance Survey 2007/08

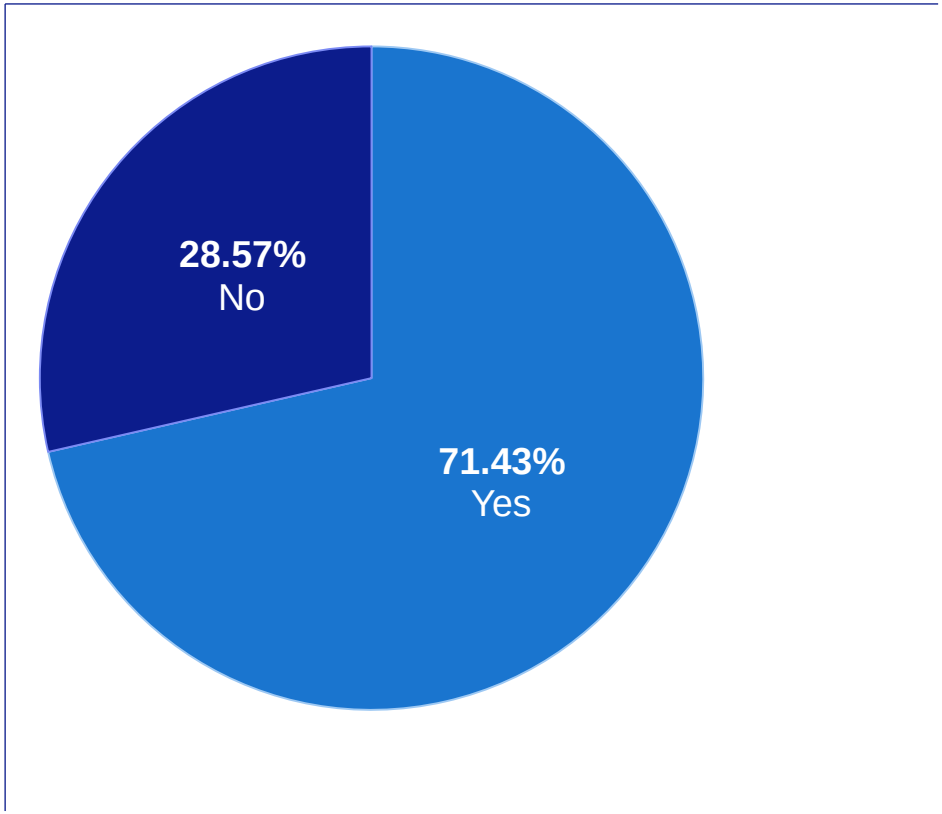
Base: All respondents (medical device and pharmaceutical organizations, 102)

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)

- In order of frequency, respondents indicates they these areas are their top compliance priorities:
  1. Distributor relationships
  2. FCPA program
  3. Due diligence programs
  4. International Ethics Code
  5. Regulatory issues / approvals
  6. Third parties (CSOs / CROs)
- Regionally, Asia-Pacific is the top compliance priority
- 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.

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

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

- 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

Worldwide contact information

35* offices in 25 countries

Abu Dhabi
Clifford Chance
9th Floor
Al Sila Tower
Sowwah Square
PO Box 26492
Abu Dhabi
United Arab Emirates
Tel +971 (0)2 613 2300
Fax +971 (0)2 613 2400

Amsterdam
Clifford Chance
Droogbak 1A
1013 GE Amsterdam
PO Box 251
1000 AG Amsterdam
The Netherlands
Tel +31 20 7119 000
Fax +31 20 7119 999

Bangkok
Clifford Chance
Sindhorn Building Tower 3
21st Floor
130-132 Wireless Road
Pathumwan
Bangkok 10330
Thailand
Tel +66 2 401 8800
Fax +66 2 401 8801

Barcelona
Clifford Chance
Av. Diagonal 682
08034 Barcelona
Spain
Tel +34 93 344 22 00
Fax +34 93 344 22 22

Beijing
Clifford Chance
33/F, China World Office 1
No. 1 Jianguomenwai Dajie
Chaoyang District
Beijing 100004
China
Tel +86 10 6535 2288
Fax +86 10 6505 9028

Brussels
Clifford Chance
Avenue Louise 65 Box 2
1050 Brussels
Belgium
Tel +32 2 533 5911
Fax +32 2 533 5959

Bucharest
Clifford Chance Badea
Excelsior Center
28-30 Academiei Street
12th Floor, Sector 1
Bucharest, 010016
Romania
Tel +40 21 66 66 100
Fax +40 21 66 66 111

Casablanca
Clifford Chance
169, boulevard Hassan 1er
Casablanca 20000
Morocco
Tel +212 520 132 080
Fax +212 520 132 079

Doha
Clifford Chance
QFC Branch
Suite B, 30th floor
Tornado Tower
Al Funduq Street
West Bay PO Box 32110
Doha
State of Qatar
Tel +974 4491 7040
Fax +974 4491 7050

Dubai
Clifford Chance
Building 6, Level 2
The Gate Precinct
Dubai International Financial Centre
PO Box 9380
Dubai
United Arab Emirates
Tel +971 4 362 0444
Fax +971 4 362 0445

Düsseldorf
Clifford Chance
Königsallee 59
40215 Düsseldorf
Germany
Tel +49 211 43 55-0
Fax +49 211 43 55-5600

Frankfurt
Clifford Chance
Mainzer Landstraße 46
60325 Frankfurt am Main
Germany
Tel +49 69 71 99-01
Fax +49 69 71 99-4000

Hong Kong
Clifford Chance
28th Floor
Jardine House
One Connaught Place
Hong Kong
Tel +852 2825 8888
Fax +852 2825 8800

Istanbul
Clifford Chance
Kanyon Ofis Binasi Kat 10
Büyükdere Cad. No. 185
34394 Levent
Istanbul
Turkey
Tel +90 212 339 0001
Fax +90 212 339 0098

Kyiv
Clifford Chance
75 Zhylyanska Street
01032 Kyiv
Ukraine
Tel +380 44 390 5885
Fax +380 44 390 5886

London
Clifford Chance
10 Upper Bank Street
London, E14 5JJ
United Kingdom
Tel +44 20 7006 1000
Fax +44 20 7006 5555

Luxembourg
Clifford Chance
2-4 place de Paris
B.P. 1147
L-1011 Luxembourg
Grand-Duché de Luxembourg
Tel +352 48 50 50 1
Fax +352 48 13 85

Madrid
Clifford Chance
Paseo de la Castellana 110
28046 Madrid
Spain
Tel +34 91 590 75 00
Fax +34 91 590 75 75

Milan
Clifford Chance
Piazzetta M.Bossi, 3
20121 Milan
Italy
Tel +39 02 806 341
Fax +39 02 806 34200

Moscow
Clifford Chance
Ul. Gasheka 6
125047 Moscow
Russian Federation
Tel +7 495 258 5050
Fax +7 495 258 5051

Munich
Clifford Chance
Theresienstraße 4-6
80333 Munich
Germany
Tel +49 89 216 32-0
Fax +49 89 216 32-8600

New York
Clifford Chance
31 West 52nd Street
New York, NY 10019-6131
USA
Tel +1 212 878 8000
Fax +1 212 878 8375

Paris
Clifford Chance
9 Place Vendôme
CS 50018
75038 Paris Cedex 01
France
Tel +33 1 44 05 52 52
Fax +33 1 44 05 52 00

Perth
Clifford Chance
Level 7, 190 St Georges Terrace
Perth, WA 6000
Australia
Tel +618 9262 5555
Fax +618 9262 5522

Prague
Clifford Chance
Jungmannova Plaza
Jungmannova 24
110 00 Prague 1
Czech Republic
Tel +420 222 555 222
Fax +420 222 555 000

Rome
Clifford Chance
Via Di Villa Sacchetti, 11
00197 Rome
Italy
Tel +39 06 422 911
Fax +39 06 422 91200

São Paulo
Clifford Chance
Rua Funchal 418 15th Floor
04551-060 São Paulo SP
Brazil
Tel +55 11 3019 6000
Fax +55 11 3019 6001

Seoul
Clifford Chance
21st Floor, Ferrum Tower
66 Sooha-dong
Jung-gu, Seoul 100-210
Korea
Tel +82 2 6353 8100
Fax +82 2 6353 8101

Shanghai
Clifford Chance
40th Floor
Bund Centre
222 Yan An East Road
Shanghai 200002
China
Tel +86 21 2320 7288
Fax +86 21 2320 7256

Singapore
Clifford Chance
12 Marina Boulevard
25th Floor Tower 3
Marina Bay Financial Centre
Singapore 018982
Tel +65 6410 2200
Fax +65 6410 2288

Sydney
Clifford Chance
Level 16
No. 1 O'Connell Street
Sydney NSW 2000
Australia
Tel +612 8922 8000
Fax +612 8922 8088

Tokyo
Clifford Chance
Akasaka Tameike Tower, 7th Floor
17-7 Akasaka 2-Chome
Minato-ku, Tokyo 107-0052
Japan
Tel +81 3 5561 6600
Fax +81 3 5561 6699

Warsaw
Clifford Chance
Norway House
ul. Lwowska 19
00-660 Warszawa
Poland
Tel +48 22 627 11 77
Fax +48 22 627 14 66

Washington, D.C.
Clifford Chance
2001 K Street NW
Washington, DC 20006 - 1001
USA
Tel +1 202 912 5000
Fax +1 202 912 6000

Riyadh**
(Co-operation agreement)
Al-Jadaan & Partners Law Firm
Building 15, The Business Gate
King Khaled International Airport Road
Cordoba District, Riyadh, KSA.
PO Box 3515, Riyadh 11481,
Kingdom of Saudi Arabia
Tel +966 11 250 6500
Fax +966 11 400 4201

* Clifford Chance's offices include a second office in London at 4 Coleman Street, London EC2R 5JJ.
**The Firm also has a co-operation agreement with Al-Jadaan & Partners Law Firm in Riyadh.

Clifford Chance, Königsallee 59, 40215 Düsseldorf, Germany