

# Morgan Lewis

## Anti-corruption Compliance for Life Sciences Industry: Case Studies and Practical Tips

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**panelists:**

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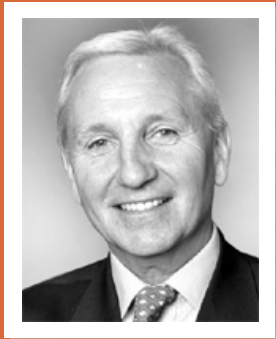
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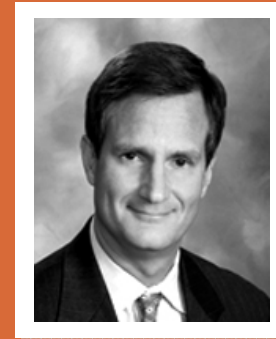
# Presenters



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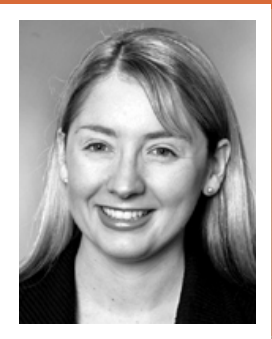
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# Topics of Discussion

- Introduction - Expansion of the Life Sciences Industry
- Increased Global Enforcement
- Anti-Corruption Enforcement in the Life Sciences Industry in:
  - U.S.
  - France
  - Germany
  - UK
- Practical Tips
- Questions

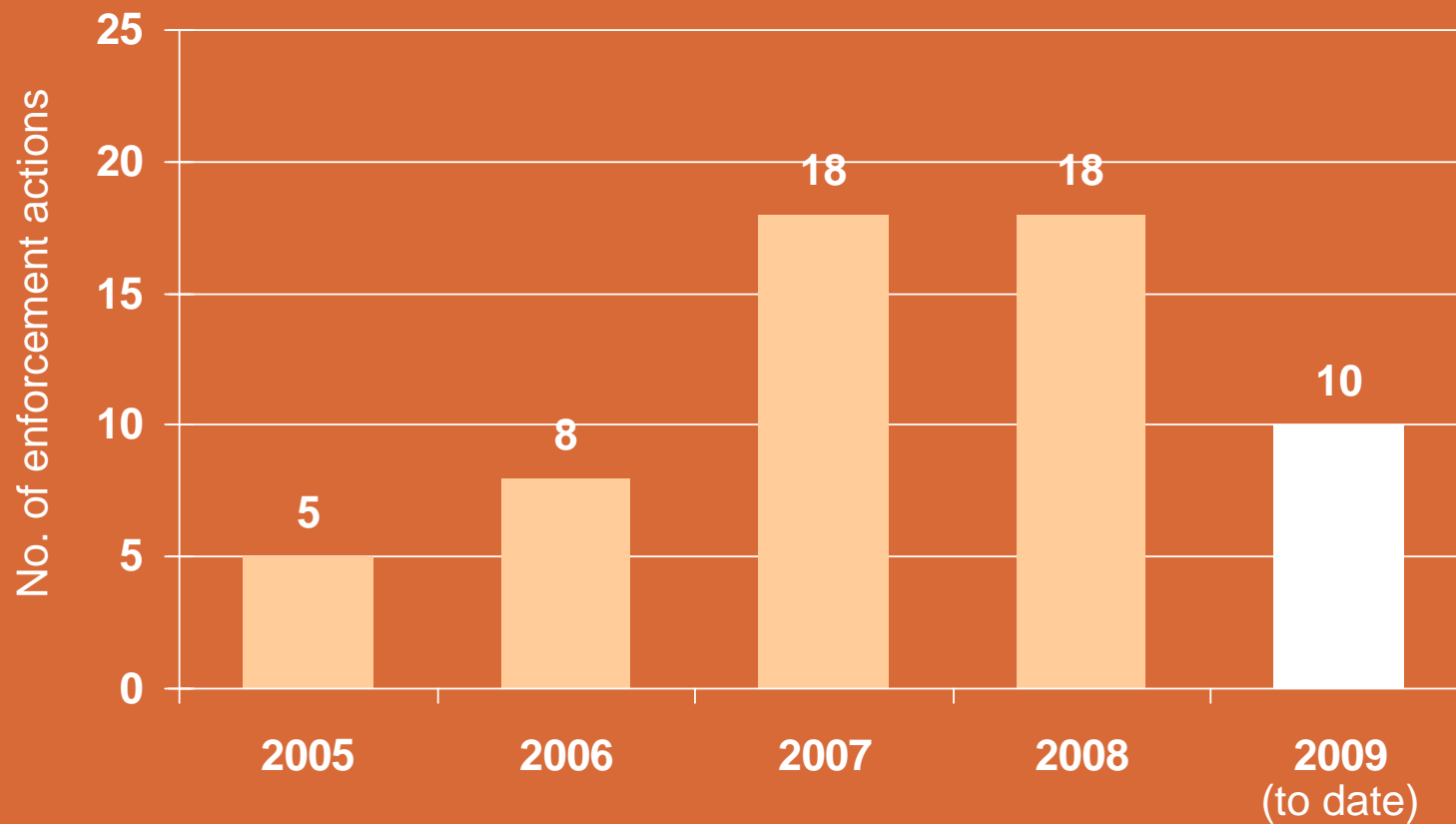
# Increased Global Enforcement

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# Increased Global Enforcement

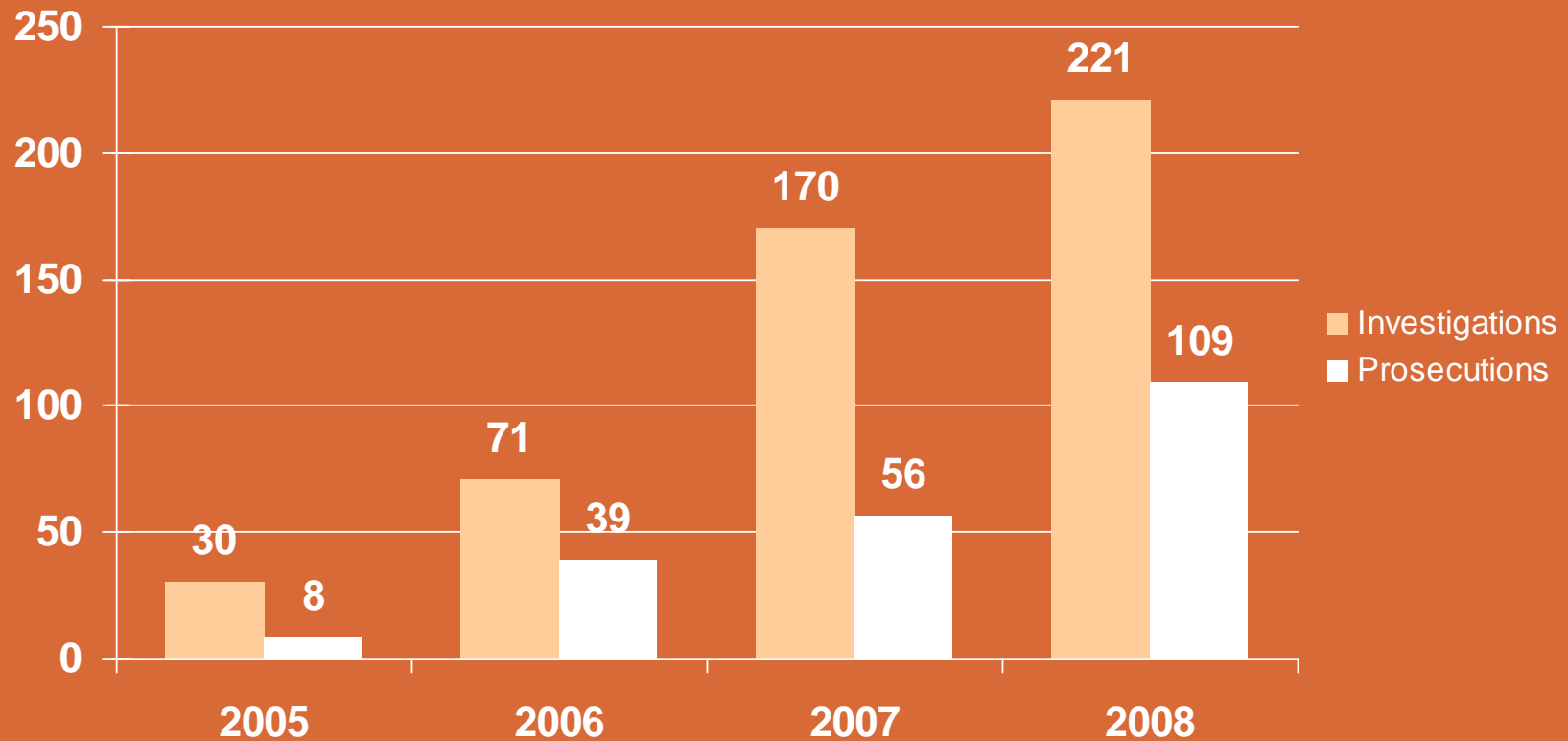
- Enforcement authorities around the globe are increasing their anti-corruption investigations and prosecutions

# U.S. Enforcement Cases (DOJ and SEC)



# More European Investigations/Prosecutions

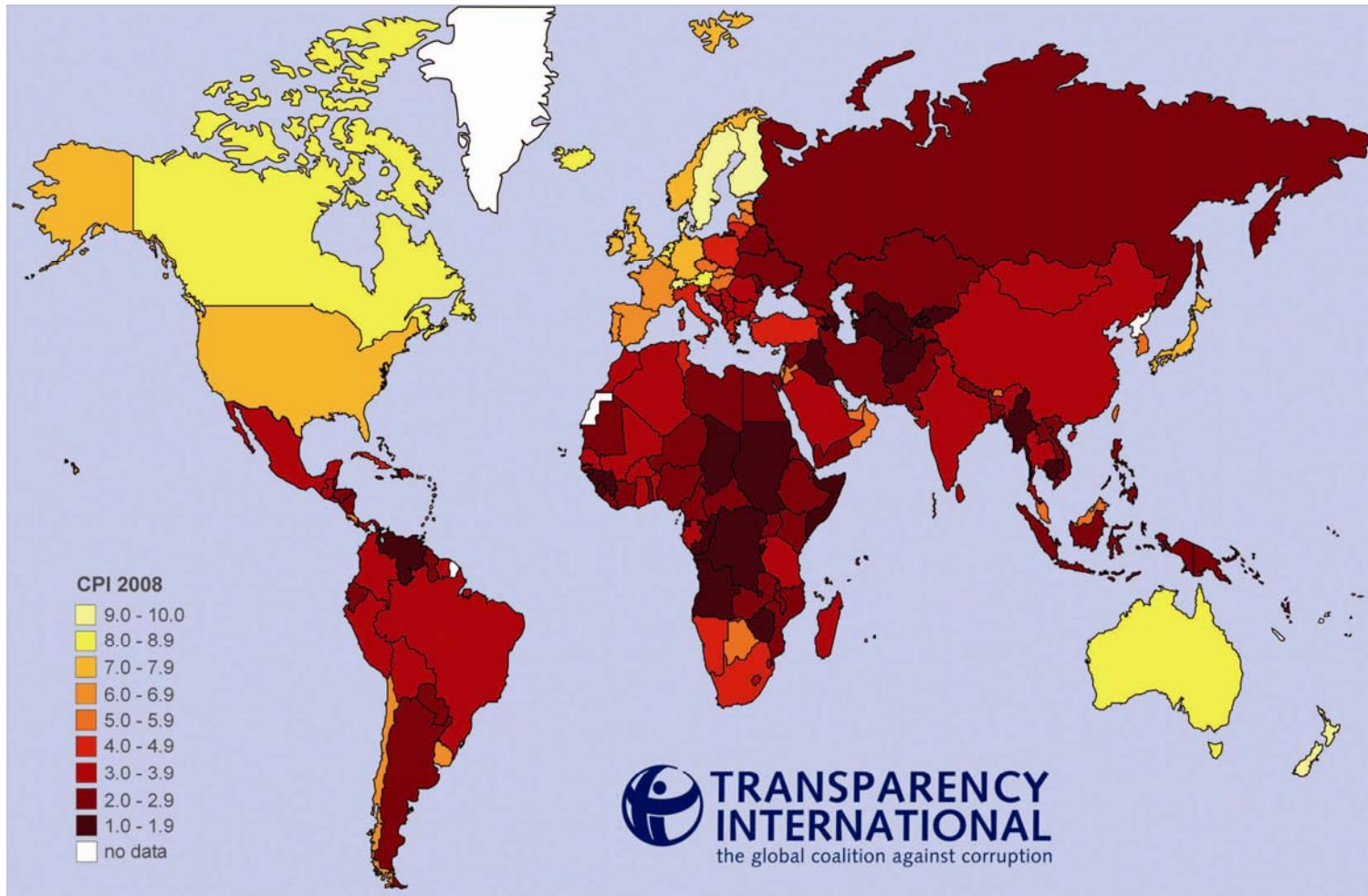
Source: Transparency International 2008 Review



# Increased Global Enforcement

- Life sciences industry is a target for anti-corruption enforcement efforts
- Increased globalization in major areas of the industry:
  - Drug discovery work
  - Drug manufacturing
  - Outsourcing of supplies
  - Conducting clinical trials
  - Distributing product

And most of this occurring. . .



# Increased Global Enforcement

- In addition, the life sciences industry has a great deal of potential contact with foreign officials:
  - Contacts with many different kinds of regulators
    - *Approvals from FDA-like agencies*
    - *Health Ministry approvals of clinical trials*
    - *Pricing and reimbursement with national public payors, including formularies*
  - Other government agencies
    - *Tax*
    - *Customs*
  - State-owned entities
    - *Any contact with a doctor employed by a state-owned hospital?*
    - *Doctor reimbursed by state payor?*

# Anti-Corruption Enforcement in the Life Sciences Industry

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# Life Sciences Investigations in the U.S.

- Categories of Anti-Corruption Investigations
  - “Oil for Food”
    - *At least three major healthcare companies under investigation*
    - *April 2009 settlement: Novo Nordisk*
  - Pharmaceutical companies
    - *At least three additional pharmaceutical companies reported active FCPA investigations*
  - Medical device
    - *“Industry” investigation*
    - *Foreign investigations initiated as result of domestic U.S. anti-kickback cases*
    - *At least seven major medical device makers announced investigations by U.S. and foreign authorities in 2007 and 2008*
    - *Investigations expected to continue to expand*

# Life Sciences Settlements in the U.S.

- Novo Nordisk (2009)
  - Oil for Food prosecution
  - Danish company paid \$19 million in penalties, fines, disgorgement, and interest for kickbacks to Iraqi government officials
- AGA Medical Corp (2008)
  - Deferred prosecution agreement with the DOJ and \$2 million penalty for payments to government-employed physicians in China to induce them to buy AGA products and to Chinese patent officials to induce them to approve AGA patent applications
- Gioacchino De Chirico & Immucor Inc. (2007)
  - De Chirico settled with the SEC in connection with a €13,500 payment to the director of a public hospital in Milan, Italy to seek contracts for supplies and equipment for Immucor
  - Immucor consented to a cease-and-desist order

# Life Sciences Settlements in the U.S.

- Micrus Endovascular Corporation (2005)
  - Deferred prosecution agreement with the DOJ
  - Unlawful payments made to physicians in France, Germany, Spain, and Turkey
- DPC (Tianjin) Ltd. (2005)
  - Foreign subsidiary of Diagnostic Products Corp. pled guilty in connection with payment of \$1.6 million in illegal “commissions” to physicians and laboratory personnel employed by government-owned hospitals in the People’s Republic of China
  - Sub paid \$2 million criminal fine; parent disgorged \$2.8 million
- Syncor Taiwan, Inc. (2002)
  - Foreign subsidiary of Syncor International pled guilty and paid \$2 million criminal fine; parent settled civil and administrative proceedings and paid a \$500,000 civil penalty
  - Conduct involved payment of commissions and referral fees to doctors at private and public hospitals in Taiwan
  - Case is known for setting precedent for pre-merger due diligence and successor liability
  - Founder and former chairman settled with the SEC in 2007

# Life Sciences Industry in France Subject to Anti-Corruption Laws

- Various legislative acts of corruption:
  - **Active** corruption of foreign public officials
  - **Passive** corruption of foreign public officials
  - International trading influence
  - Private corruption: article 445-1 of the New French Criminal Code

# EC Directives Imported into French Law

- Directive 2001/83/EC of the European Parliament and Council of 6 November 2001 on the Community Code relating to Medicinal Products for Human Use
- Directive 2004/27/EC of the European Parliament and Council of 31 March 2004 (amending above Directive)
- Importation of the Directives by article L 4113-6 of the French Public Health Code

# Article L 4113-6

## French Public Health Code

- Principle: health professionals are prohibited from receiving benefits in kind or pecuniary benefits
- Exemptions to the principle:
  - the requirement of an agreement
  - the relevant professional bodies (Conseil départemental de l'ordre)
  - the calculation of remuneration
- Notion of offered hospitality

# French Cases re: Life Sciences Companies

- Decision of Supreme Court December 17, 1999.
- Decision of Court of Appeal of Montpellier February 12, 2009.

# FCPA Life Sciences Cases Involving France

- **Micrus Corporation:**
  - Payments made by U.S. company to doctors at state-run hospitals in France (et al.) to induce purchase of products. Micrus agreed to pay \$450,000 fine, adopt FCPA compliance program and set of internal controls, and retain independent monitor for three years
- **Syncor International Corporation:**
  - French subsidiary of U.S. company made payments to doctors at state-run hospitals to obtain and retain business and referrals of patients to Syncor medical imaging centers and purchases of Syncor products. Syncor consented to pay \$500,000 and to having independent consultant audit and recommend corrective changes to company's FCPA policies and procedures

# Germany – New Legislation and “Doc Morris”

- The German Legislature continues to change the rules pursuant to which life sciences companies are allowed to sell their products
- Health insurance companies are now able to enter into fixed price agreements with pharmaceutical companies for specific drugs for the benefit of all customers
  - As a result, the entire industry (in particular, the generic industry) faces tremendous price pressure
- The ECJ upheld Germany’s legislation pursuant to which pharmacies must be run by pharmacists and not by corporations

# Germany – Recent Cases

- Germany has limited pharma companies' use of “rebates in kind” vis-à-vis pharmacies
- The attempt by a number of pharmacies to circumvent these restrictions by establishing a cooperative in Vienna (“Global Apo”) is currently being investigated
- A well-known German generic manufacturer was investigated for paying kickbacks and illegal rebates in kind to doctors
- Other well-known FCPA cases relating to the German life sciences industry include:
  - Micrus
  - Orthopedic Device Manufacturers
  - BMS

# Germany – Issues to Be Aware of

- In light of the fact that the majority of German hospitals continue to be state run, all dealings between pharma companies and hospitals provide numerous pitfalls for pharma companies subject to the FCPA
- Representatives of these hospitals are public officials within the meaning of the FCPA and national anti-corruption laws
- Even indirect benefits such as “third-party funds” may be illegal: compare German Federal Supreme Court decisions of May 23 and October 23, 2002

# Germany–Recommendations

- As a result, all agreements with hospitals should be carefully scrutinized to determine whether they can be construed as improperly influencing the procurement and prescription decisions of hospitals and staff
- This includes clinical studies and sponsoring
- Compliance with TI-Germany’s recommendations for agreements with hospitals and codes of conduct (e.g., FSA, AKG, and others) is recommended

# The Life Sciences Industry in the UK

Country	Exports £bn	Imports £bn	Balance £bn
Germany	24,395	18,810	5,586
Switzerland	20,206	9,336	10,870
USA	17,491	35,801	-18,310
<b>UK</b>	<b>14,567</b>	<b>10,291</b>	<b>4,276</b>
France	13,675	10,135	3,540

*World trade in pharmaceuticals 2007 (source: ABPI)*

# The Life Sciences Industry in the UK

Country	Sales £bn	Market Share %
USA	22,292	6.7
<b>UK</b>	<b>18,847</b>	<b>5.6</b>
SWI	17,154	5.1
FRA	16,788	5.0
<b>UK</b>	<b>15,010</b>	<b>4.5</b>

*Top world pharmaceutical companies 2007 (source: ABPI)*

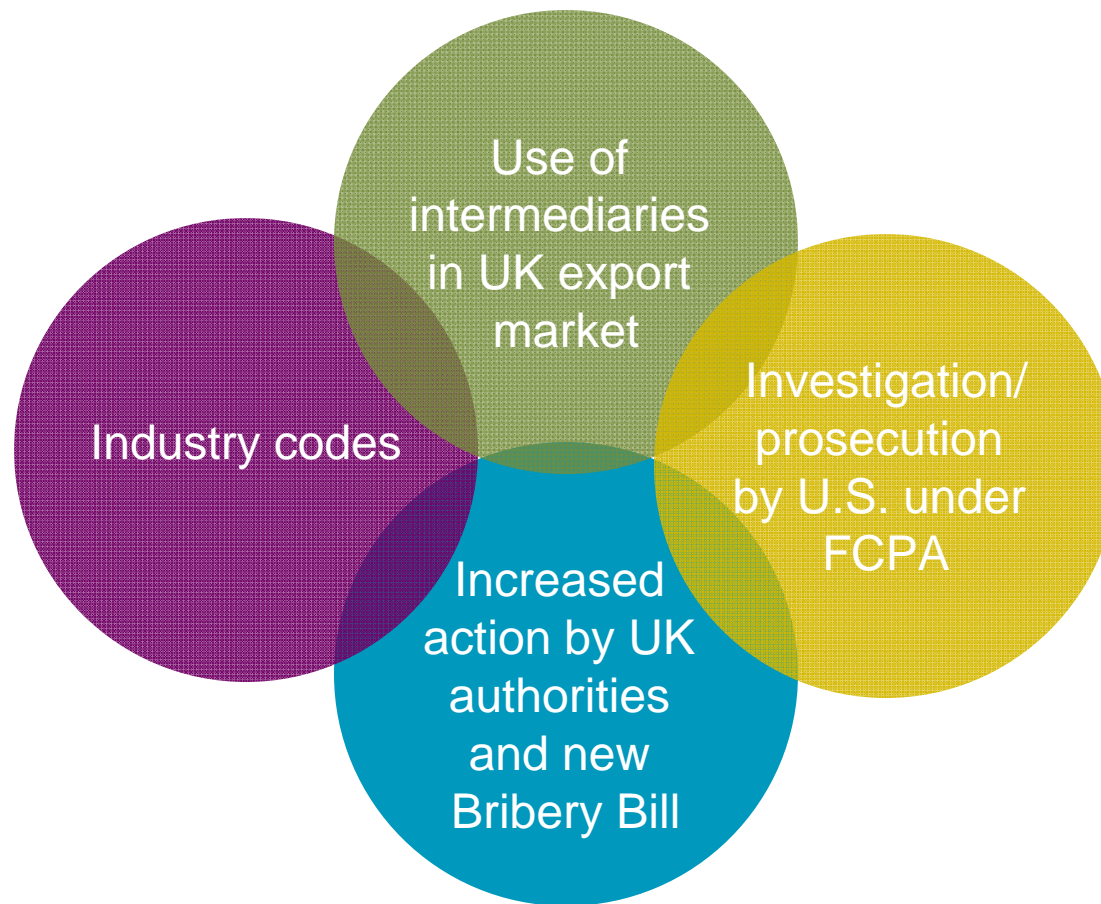
# The Life Sciences Industry in the UK

- Medical devices:
  - UK third-biggest exporter
  - UK fourth-biggest importer
  - Largest single customer in the world for medical devices is the NHS

(source: Eucomed)

# UK Life Sciences Companies at Risk

- Reasons for UK companies to be prepared:



# Current U.S. Investigations of UK Life Sciences Companies

- Under SEC investigation:
  - Two UK pharma companies (both U.S. issuers)
  - One UK medical devices company

# Recent U.S. Actions Against European Life Sciences Companies

- Novo Nordisk
  - May 2009 Danish pharma company paid \$19 million in disgorgement, interest, and penalties to SEC and DOJ re alleged kickbacks Oil for Food Program
- Akzo Nobel
  - 2007 Dutch pharma company paid nearly \$3 million in disgorgement, interest, and penalties to SEC and DOJ re alleged improper payments of “after sales service fees;” €400,000 fine also paid to Dutch authorities
- Schering-Plough
  - 2004 Polish subsidiary of a U.S. company paid \$500,000 to SEC for monies allegedly paid to Polish government official to influence purchase of products

# UK Ramping Up Enforcement Agencies and Laws for Action

- Any risk of action by UK authorities? **YES!**
  - AON fine by UK Financial Services Authority – inadequate systems and controls in place to prevent bribery
  - CBRN – first conviction by City of London Police for overseas bribery
  - Draft Bribery Bill
  - Reform at the UK Serious Fraud Office
  - Balfour Beatty – SFO use of civil remedies for payment irregularities
  - Life sciences companies currently under SFO investigation: two UK pharma companies ordered to hand over confidential documents

# UK Life Sciences Industry Codes of Practice

- Europe-wide codes to ensure proper selling and promotion practices
- In the UK:
  - ABPI’s Code of Practice for the Pharmaceutical Industry 2008
    - *Clause 18: “No gift, benefit in kind or pecuniary advantage shall be offered or given to members of the health professions or to administrative staff as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine. . .”*
  - ABHI’s Code of Business Practice
    - *Policy on Unlawful Payments and Practices states: “Members should not directly or indirectly offer, make, or authorise payment of money or anything of material value, to unlawfully (a) influence the judgment or conduct of any individual, customer, or company; (b) win or retain business; (c) influence any act or decision of any governmental official; or (d) gain an advantage.”*
- Sanctions for non-compliance, e.g. suspension or expulsion from the industry body, publication of case reports, cessation of promotion

# Why UK Life Sciences Companies Should Be Prepared!

- Indicators show UK companies should be taking proactive steps to adopt adequate systems to prevent bribery:
  - Increasing anti-corruption action being taken throughout the world against life sciences companies
  - UK life sciences companies currently facing investigations by U.S. authorities under FCPA and by the SFO
  - SFO is gearing up for increased action against UK companies
  - FSA has taken action for inadequate systems/controls to prevent bribery
  - New Bribery Bill with new corporate negligence offense
- Ignoring warning signs could mean a nasty and expensive investigation

# Practical Tips

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# Practical Tips

- Practical tips for decreasing the risk of being caught up in a government anti-corruption investigation
  - Compliance
  - Specific Due Diligence

# Practical Tips

- Compliance
  - Review current FCPA policies and procedures
  - Review current FCPA training programs
  - Review current agents/consultants
  - Review most recent FCPA audit results
  - Evaluate and update
  - Triage risk
  - Develop procedures for conducting and documenting due diligence for third-party agents, consultants, and in-country subsidiaries

# Practical Tips

- Due Diligence for Agents and Consultants
  - Review whether red flags exist
    - *Are they state-owned facility employees or government officials?*
    - *Do they claim to be related to or to have influence over government officials?*
    - *Have they refused to confirm that they understand the FCPA and will comply?*
    - *Have they requested cash payments or that payments be made to third-party accounts?*
    - *Are they requesting a “success fee” for their services? Is their fee request consistent with industry practice?*

# Practical Tips

- Due Diligence for Agents and Consultants
  - Create due diligence file for each agent and consultant containing:
    - *Contract*
    - *Reasons for hiring*
    - *Experience/resume*
    - *Review of risk factors*
    - *Justification for payments*
    - *Reports*
    - *Backup for any expenses*
    - *Reference check*
    - *AML and Designated Persons check*

# Practical Tips

- Due Diligence for Acquisitions
  - Determine the adequacy of the target’s compliance policies and procedures
  - Review the target’s sales history with state-owned hospitals or healthcare facilities (including payments to physicians or other healthcare employees)
  - Review financial records to determine any suspicious payments, including but not limited to large cash payments or unusual “commissions”
  - Determine whether the target’s country of operation has a history of corruption

# Questions

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