



KOL Liaison and MSL Best Practice Conference

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Introduction

- Pre-Bribery Act 2010
- Bribery Act 2010
- Effects, likely interpretation and practical implications
- Legality



Pre-Bribery Act 2010

Pre-Bribery Act 2010

- Role of Key Opinion Leaders (KOLs)
- Significance to the pharmaceutical industry
- Issues

Pre-Bribery Act 2010

- Role of KOL's
 - KOLs - **academic researchers** and **influential specialist physicians** that effectively convey media messages to their peers
 - KOLs' **opinions** can be **used to market drugs** e.g disseminate key clinical findings
 - KOLs' may be **paid to speak** and **write** on behalf of pharmaceutical company
 - Lend names to articles - **ghost writers**
 - **Principal investigators** on studies

Pre-Bribery Act 2010

- Pharmaceutical industry - Significance of KOLs
 - Establish desperate need for drugs
 - Spin clinical-trial results to their advantage
 - Downplay the side effects of drugs
 - Neutralise critics; or
 - Emphasise drugs off-label uses

Pre-Bribery Act 2010

- The industry spends just under a third of its total marketing expenditure on KOLs. (*The Secret Lives of Big Pharma's 'Thought Leaders'* –by Carl Elliot in Sept 2010)
- “Regardless of training, virtually all pharmaceutical companies realize the important role opinion leaders play in the communication of key product information to the healthcare community.” (*Fulfilling the Spectrum of Needs in Opinion Leader Solutions’* article in NGP Issue 7 (January 2007))

Pre-Bribery Act 2010

■ Issues

- Drug companies provide **corporate hospitality**, gifts and other expenses to KOLs (“**promotional expenses**”)
- KOLs may **not act in the patients best interest** - encouraging or favouring the prescription of less effective drugs for treatment of certain conditions
 - Due to physicians’ **close relationship with pharma**; or
 - Lavish treatment or gifts from pharma
 - Ethical loyalties of physicians may be divided between patients and pharma
- *We recommend KOL should be obliged to declare significant sums or gifts they receive as Hospitality - ‘The Influence of the Pharmaceutical Industry- House of Commons Health Committee’ [2005].*



Introduction of the Bribery Act

Introduction of the Bribery act

- When did it come in?
- What was the intention behind the Act?
 - Not to criminalise bona fide, proportionate and reasonable hospitality, promotional and other business expenditure (Adequate Procedures Guidance)
- Main offences
- Effect on “promotional expenses”?
- How is it prosecuted?

Introduction of the Bribery act

- Main offences
 - Section 1 - Bribing other people
 - Section 2 - Being bribed
 - Section 7 - Failure of commercial organisations to prevent bribery
 - Section 6 - Bribery of foreign public officials

Main Offences

■ Section 1 - Bribing another person

“General bribery offences

1. *Offences of bribing another person*

(1) A person (“P”) is **guilty of an offence** if *either* of the following cases applies.

(2) Case 1 is where—

(a) P **offers, promises or gives a financial or other advantage** to another person, **and**

(b) P **intends the advantage**—

(i) to **induce** a person to **perform improperly a relevant function or activity**, or

(ii) to **reward** a person for the **improper performance of such a function or activity**.

- In relation to provision of corporate hospitality or promotional expenses in a commercial context, the hospitality must:
 - Provide an **advantage** to another person; and
 - Be given with the intention of **inducing** the person to perform a **relevant function** improperly or **knowledge** that acceptance of the advantage is, in itself, **improper performance**.

Main Offences

■ What is a ‘relevant function’

- Section 3 of the Act
- *A function or activity is a ‘relevant function or activity’ if it is:-*
 - (1) *any function of a **public nature**;*
 - (2) *any **activity connected with a business**;*
 - (3) *any activity performed in the course of a **person's employment**; or*
 - (4) *any activity **performed by or on behalf of a body of persons** (whether corporate or unincorporate)*

Main Offences

- *To be a ‘relevant function or activity’, the function or activity should **also** meet one of the following conditions:-*
 - (A) *the person performing the function or activity is expected to perform it in good faith;*
 - (B) *the person performing the function or activity is expected to perform it impartially;*
 - (C) *the person performing the function or activity is in a position of trust by virtue of performing it.*

Main Offences

- Meaning of ‘improperly performed’ - Section 4(1) of the Act
 - A relevant function or activity is performed **improperly** if it is performed in breach of a ‘**relevant expectation**’
 - Meaning a person will act in good faith, impartially, or in accordance with a position of trust.

Main Offences

- Section 2 - Being bribed
 - Person commits an offence if take a bribe and one of the following is satisfied:
 - Take the bribe **intending to perform a relevant function improperly** (Section 2(2));
 - **Taking the bribe itself** constitutes **improper performance** of a relevant function (Section 2(3));
 - The bribe is intended to **reward improper performance** of a relevant function (Section 2(4));
 - In **anticipation or in consequence of taking** the bribe, a **relevant function has been performed improperly** (Section 2(5)).

Main Offences

■ Section 7 - Failure of commercial organisations to prevent bribery

- (1) A relevant commercial organisation (“C”) is guilty of an offence under this section *if a person (“A”) associated with C bribes another person intending—*
- (a) to *obtain or retain business for C, or*
 - (b) to *obtain or retain an advantage in the conduct of business for C.*
- (2) *But it is a defence for C to prove that C had in place adequate procedures designed to prevent persons associated with C from undertaking such conduct.*
- Offence for commercial organisation to fail to prevent a person associated with it from bribing on its behalf
 - Strict liability
 - Of most significance to pharmaceutical industry
 - Defence: If organisation can show it had adequate procedures in place to prevent persons associated with C from doing such conduct (Section 7(2))

Main Offences

- Breadth of drafting, particularly definitions “commercial organisation” and “associated persons”, means UK pharmaceuticals companies should consider their global activities carefully

“relevant commercial organisation” means—

- (a) a body which is incorporated under the law of any part of the United Kingdom and which carries on a business (whether there or elsewhere),
- (b) any other body corporate (wherever incorporated) which carries on a business, or part of a business, in any part of the United Kingdom,
- (c) a partnership which is formed under the law of any part of the United Kingdom and which carries on a business (whether there or elsewhere), or
- (d) any other partnership (wherever formed) which carries on a business, or part of a business, in any part of the United Kingdom, and, for the purposes of this section, a trade or profession is a business.

Main Offences

“Associated persons” - any person who performs services for or on behalf of an organisation.

- In the pharmaceutical industry this could include e.g. KOLs, sales representatives, regulatory consultants in emerging markets, agents
- **Risks**
 - Pharma falls within a ‘relevant commercial organisation,’ even if its partnership has not been formed in the UK but it carries on a business in the UK. Burden on pharma:
 - to conduct **due diligence** on any **associated persons** they intend to contract with;
 - awareness of **policies and procedures**
 - conduct **training**

Main Offences

■ Section 6 - Bribery of foreign public officials

6. Bribery of foreign public officials

(1) A person (“P”) who **bribes a foreign public official** (“F”) is guilty of an offence if P’s **intention is to influence F in F’s capacity as a foreign public official**.

(2) P must **also intend to obtain or retain**—

(a) **business**, or

(b) **an advantage in the conduct of business**.

(3) P **bribes F** if, and only if—

(a) **directly or through a third party, P offers, promises or gives any financial or other advantage**—

(i) to F, or

(ii) to **another person at F’s request or with F’s assent or acquiescence**, and

(b) **F is neither permitted nor required by the written law applicable to F to be influenced in F’s capacity as a foreign public official by the off**

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Main Offences

- Why would section 6 be relevant?
 - Doctors in countries such as China are almost all employed by the government, could pose a great problem for the KOL-Pharma relationships under the Bribery Act
 - If pharma intend to sponsor/donate money to KOLs in other countries then they should select these KOLs carefully
 - Section 6 of the Act could impede the vital interaction between the industry and government-employed health care professionals and have far-reaching ramifications

Effect on “promotional expenses”

- Of particular relevance to pharma
- Perceived effect of the Bribery Act:
 - Pharma no longer able to provide corporate hospitality as pharma would like and this could be detrimental to business
 - Organisations not subject to it will have a competitive advantage.

Effect on “promotional expenses”

- Impact of Section 1 on promotional expenses/corporate hospitality:
 - Providing an advantage
 - Not likely this would include paying **legitimate expenses** of a supplier or customer so that they can visit a facility for business reasons
- Impact of Section 6 on promotional expenses/corporate hospitality:
 - Different standard applied compared to Section 1
 - Providing an advantage
 - Not likely this would include paying **legitimate expenses** of a supplier or customer so that they can visit a facility for business reasons

Effect on “promotional expenses”

- Impact of Section 6 on promotional expenses/corporate hospitality:
 - Frequent dealings only with KOLs is usually to further business interests, therefore the intention to gain business/business advantage might be inferred from any course of dealing
 - Critical point to consider:
 - Arguable that the **hospitality, in itself**, is intended to **influence the KOL**?
 - Factors to consider:
 - Is hospitality commensurate with that provided by others?
 - Is it beyond what might reasonably be expected by the KOL/relevant sector?
 - Is it likely to have a bearing on the KOL’s decision making?

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Effect on “promotional expenses”

- **Impact of Section 6 on promotional expenses/corporate hospitality:**
 - Adequate Procedures Guidance notes that different sectors have different norms as to the levels of hospitality

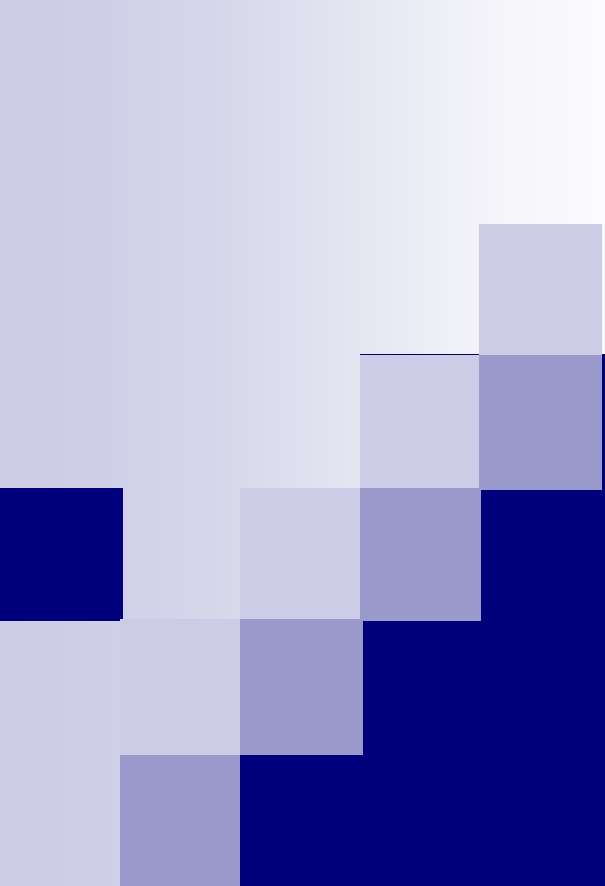
 - Emerging markets and the pharma industry:
 - The value of emerging markets to the industry has increased significantly
 - These markets may have local custom and practice which includes conferring benefits/facilitation payments
 - Would these be covered under the Act?
 - Would they be viewed as norm?

Effect on “promotional expenses”

- Impact of Section 2 on promotional expenses/corporate hospitality:
 - Similar to Section 1

How is it prosecuted?

- The Serious Fraud Office is chiefly responsible for enforcing the Bribery Act
- Prosecution has to show that the hospitality was **intended** to bring about the **improper performance** and that this would be **judged** by what a **reasonable person** in the UK would think
- With regards to section 1, the improper performance intention requirement poses a high threshold before the SFO might consider prosecuting.



**Effect, likely
interpretation and
practical implications**

Effect, likely interpretation and practical implications

- Pharma could now be held liable if do not have certain procedures in place to limit bribery
 - This could simply be the proffering of financial or other advantages by a pharmaceutical company to KOLs, but only if it results in the KOLs performing an act improperly.
- Competitors could have a major competitive advantage over those with operations in the UK, particularly in markets where enforcement of local anti-bribery laws is perceived to be weak - GSK view (2010)
- Companies will be liable under the Bribery Act only if the hospitality is intended to induce the client to perform a function improperly.
- Association of the British Pharmaceutical Industry's code of practice was updated to include a restriction on promotional giveaways (from May 2011) and requirements to declare payments to doctors and funding to attend medical congresses (in 2013)...

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Effect, likely interpretation and practical implications

- *In a letter on the Bill as it was going through Parliament, it was stated that ‘the Government is not seeking to penalise expenditure on corporate hospitality for legitimate commercial purposes. But lavish corporate hospitality can be used as a bribe to secure advantages and the offences in the Bill must therefore be capable of penalising those who use it for such purposes.’ (Lord Tunncliffe, 14 January 2010).”*
- Other Regulations/Guidance:
 - ABPI Code
 - Practical steps for KOL’s



Legality

Legality

- What needs to be changed to ensure relationships are conducted in a legal manner?
 - Bribery Act and ABPI make it clear that certain promotional items can no longer be distributed to KOLs - induce them to form a biased opinion towards certain drugs or companies
 - If ABPI guidelines are closely followed then pharma can still promote products through KOLs - limited means (restrictions on giveaways *May 2011 requirements to declare payments to doctors and funding to attend medical congresses*)
 - KOL's should also be wary of accepting lavish gifts and promotional items that don't abide by these standards in order to minimise liability

Legality

ABPI Codes

- “18.1 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, subject to the provisions of Clauses 18.2 and 18.3.
- ...
- 18.3 Health professionals and appropriate administrative staff attending scientific meetings and conferences, promotional meetings and other such meetings may be provided with inexpensive notebooks, pens and pencils for use at such meetings. They must not bear the name of any medicine or any information about medicines but may bear the name of the company providing them.
- Page 28:
“A promotional aid is defined as a non-monetary gift made for a promotional purpose. Promotional aids may be given to health professionals and administrative staff only in accordance with Clause 18.3.
... Items to be passed on to patients may bear the name of a medicine and/or information about medicines only if such detail is essential for the proper use of the item by patients. Items for the personal benefit of health professionals or administrative staff must not be offered or provided. Many items given as promotional aids in the past are no longer acceptable. These include coffee mugs, stationery, computer accessories such as memory sticks, diaries, calendars and the like.
- Items for use with patients in the clinic, surgery or treatment room etc are also no longer acceptable. These include surgical gloves, nail brushes, tongue depressors, tissues and the like.
- Items such as toys and puzzles intended for children to play with may no longer be provided.
- Items for use in the home or car remain unacceptable. Examples include table mats, coasters, clocks, desk thermometers, fire extinguishers, rugs, thermos flasks, coffee pots, tea pots, lamps, travel adaptors, toolboxes, umbrellas, neck cushions, plant seeds, road atlases and compact discs of music.
- “Pharmaceutical companies can no longer give diaries and desk pads etc to health professionals and appropriate administrative staff but there is nothing to prevent them being given by other parties which are not pharmaceutical companies. In the past these have sometimes carried advertisements for prescription medicines but this is now not acceptable. Advertisements for prescription medicines must not appear on any items which pharmaceutical companies could not themselves give.”
 - You CAN however provide health professionals and appropriate administrative staff with memory sticks and DVDs, provided that the former is of a storage size corresponding to the amount of data to be stored and that the latter can't be used by the recipient to store other data (page 29).

Textbooks CAN'T be used as promotional aids ■

Legality

- Pharma can distribute items or promotional aids to KOLs that may bear company logos- **brands or names of drugs cannot appear on these aids**
- If pharma put into place clear guidelines to be followed by KOLs- acts which may be perceived as bribery are distinguished and can be avoided
- Employees and KOLs should be trained and brought up-to-date with recent amendments
 - They should be informed of the reformation of old processes and be made aware of the acts of committing bribery (both by offering and accepting bribes) so that the company and KOL's (see section 2 of the act) are not held liable
 - KOLs should also review contracts of employment to ensure not in breach (*Nottingham v Fishel [2000]*, not clear whether a KOL))

Legality

- **What can be done to ensure hospitality and promotional expenditure is legitimate?**
 - See Adequate Procedures Guidance and Bribery Act Prosecution Guidance
 - SFO Former General Counsel, Vivian Robinson QC makes some additional points:
 - Publish clear written policies prohibiting gifts, expenses or hospitality.
 - Guidance on upper limits for gifts, hospitality and/or expenses.
 - Policy and procedures and guidance communicated to employees.
 - Gifts, hospitality and expenses should be fully documented.

Legality

- **Guidance from Ministry of Justice (6 Principles):**
 - Proportionality – action taken should be proportionate to risks
 - Top Level Commitment – senior management should take the lead
 - Risk Assessment – perform proper assessment of any bribery risks faced
 - Due Diligence – adequate checks on those engages for business dealings
 - Communication – All staff are aware of and familiar with policies and procedures
 - Monitoring and Review



Conclusion

Conclusion

- Bribery Act has serious ramifications
- Compliance with ABPI may not be enough on its own
- Pharma to adopt adequate procedures and policies
- Due diligence and regular checks

Further Information

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