PRECONFERENCE I - COMPLIANCE 101 WORKSHOP
ASIA PACIFIC PHARMA CONGRESS
WEDNESDAY SEPTEMBER 21 2016
SINGAPORE

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BASIC COMPLIANCE TRAINING

Masood Ahmed

Vice President

Regional Compliance Officer Asia /JPAC

Sanofi Group

Disclaimer: Sanofi Group is not responsible for any of presented materials or opinions I will express during my presentation.

Basic Compliance Training

a. Role Of Compliance Committee !

Basic Compliance Training

What is Monitoring & Program Oversight ?

Basic Compliance Training

Monitoring :

On Site Observation

Desk Audit

Exceptional Reporting

Basic Compliance Training

Data Analytics Tools

Forensic Analysis

Basic Compliance Training

Major Challenges;

1. Technology
2. Investment
3. Competency
4. Commitment

PRIVACY AND DATA PROTECTION

Andrew Ho

DISCLAIMER

The views and comments I will present are of **my own** and do not reflect the views or comments of my employer Sanofi or any other company.

WHAT IS PRIVACY?

Privacy is the ability of an individual or group to seclude themselves, or control any information about themselves, and thereby express themselves selectively.

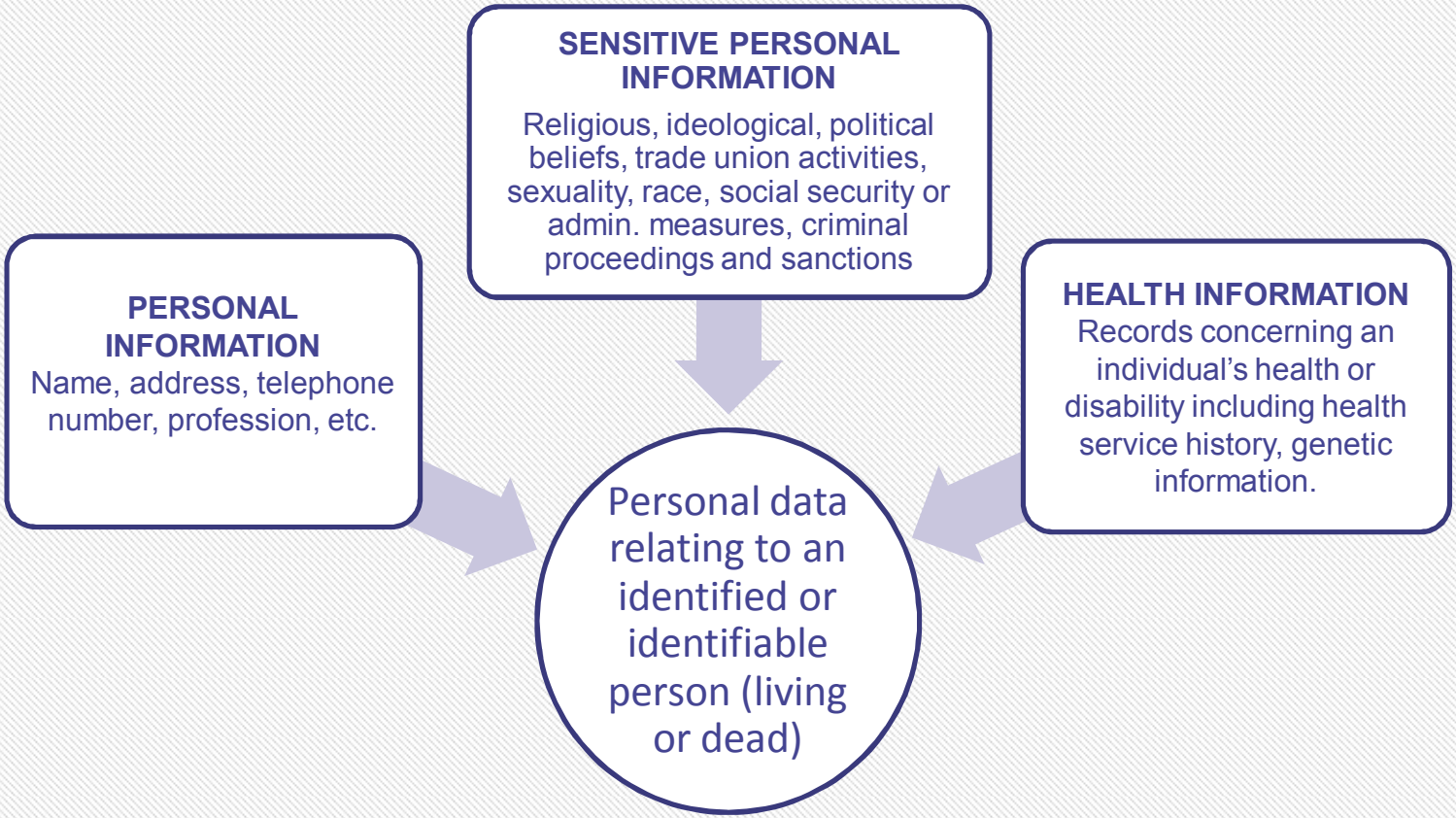
WHAT IS DATA PROTECTION?

Data protection is commonly defined as the law designed to protect your personal information, which is collected, processed and stored by “automated” means or intended to be part of a filing system.

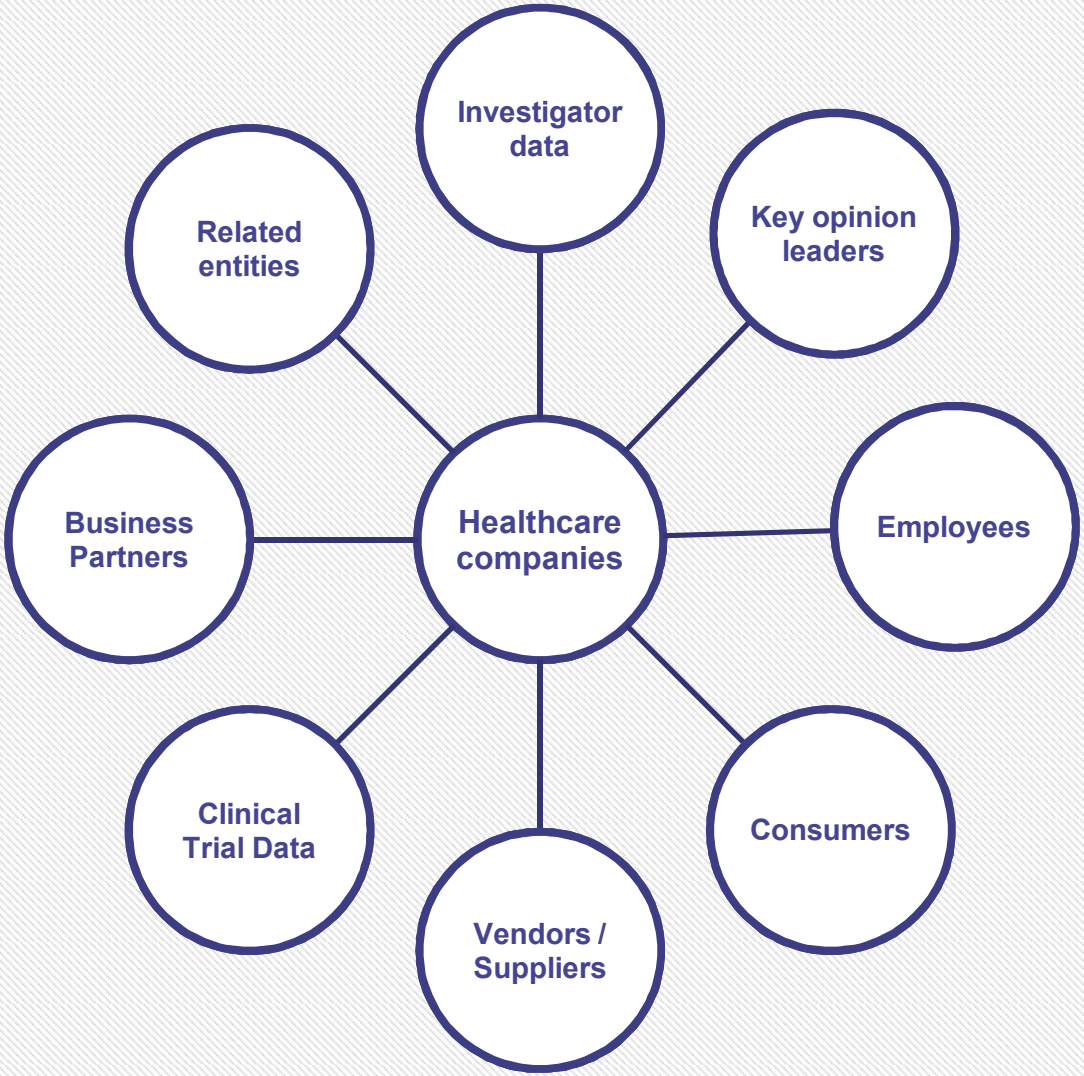
Data Protection ensures that data collected by a company was collected transparently, used for the correct agreed purpose and protected against any potential breach or misuse.

Source: privacyinternational.org

WHAT KIND OF INFORMATION IS IN SCOPE?



PERSONAL DATA CAN COME FROM ALL AREAS



WHY IS PERSONAL DATA PROTECTION SO IMPORTANT IN HEALTHCARE?

- **WE'RE AN INDUSTRY FOUNDED ON TRUST AND INTEGRITY.**
- **ENABLES CLINICAL TRIALS AND MARKET RESEARCH**. Individuals are more likely to participate research if they believe that their privacy is being protected.
- **SENSITIVITY OF HEALTH INFORMATION.** Degree of harm and reputational damage from health information being leaked is extreme.
- **NECESSARY BUSINESS FUNCTIONS** E.g. Call notes, Adverse event reporting, transparency.

CONSIDERATIONS IN HEALTHCARE

Patient data in Clinical Trials, e.g. use of analytics

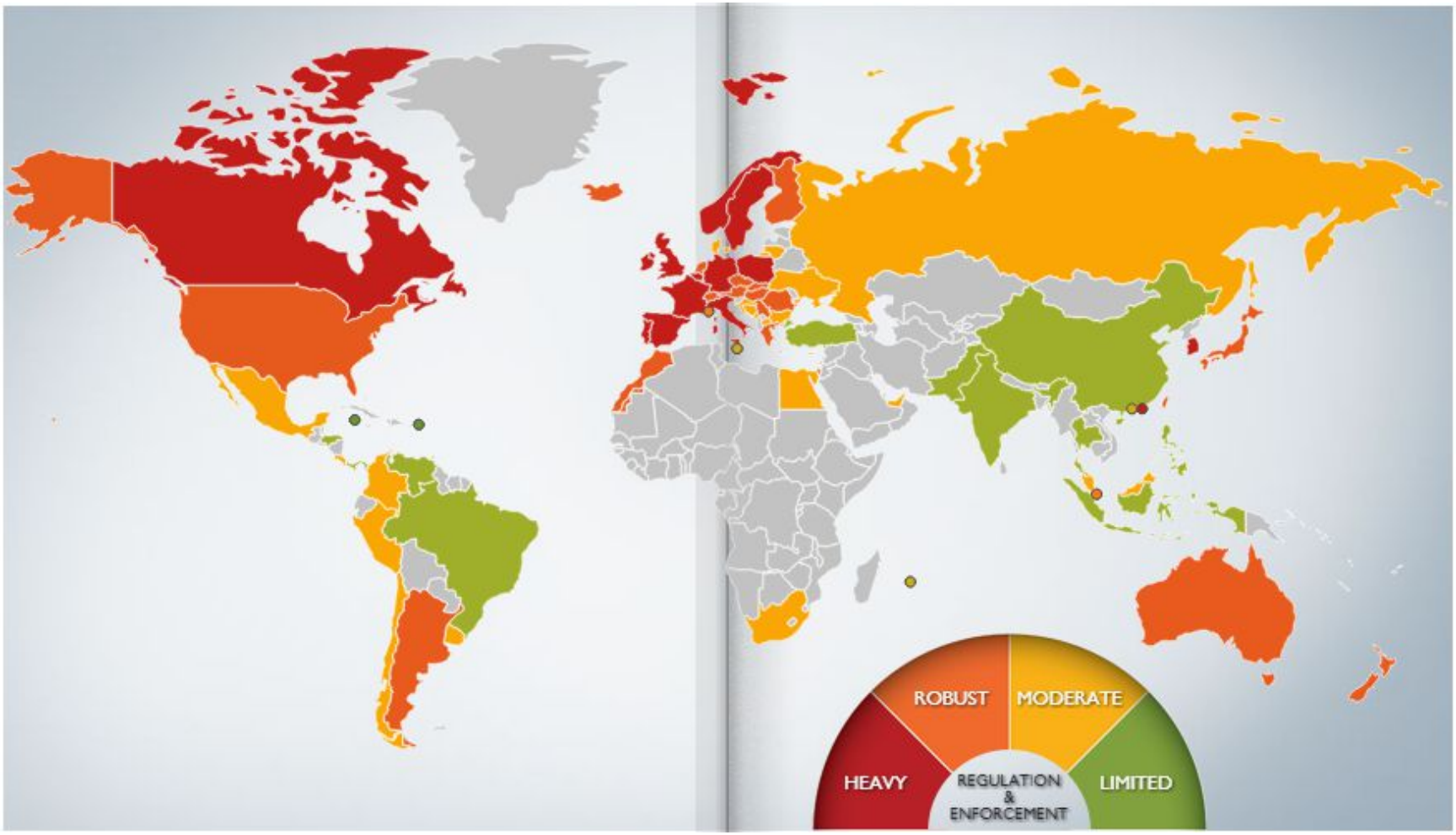
Employee HR data, e.g. sickness, involvement in compliance investigations

Internal / external Reporting Lines

Case notes regarding compliance investigations, whether proven or not

HCP data in Field Automation Systems / Reps' "little black books"…

Disclosures / Transparency Reporting for



Source:
http://dlapiperdataprotection.com/#handbook/world-map-section/c1_AU

WHAT COULD GO WRONG?

Telstra fined, warned after new privacy breach

THE AUSTRALIAN | MARCH 11, 2014 10:20AM

SAVE

Mitchell Bingemann
Reporter
Sydney

Follow @Mitch_Hell

TELSTRA has been fined $10,200 and warned over privacy breaches after an information leak exposed almost 16,000 of its customers' private data online.

In a joint investigation by the federal Privacy Commissioner and the communications watchdog, Telstra was found to have breached the Privacy Act by exposing online the data of some 15,775 Telstra customers, including 1257 silent line customers, when the telco giant failed to adequately protect the information.

The breach, discovered in May last year, meant that private customer data including names, telephone numbers and home and business addresses could be found through simple Google searches.

12 tips to implementing a robust and compliant Personal Data Protection Program

1. Have a detailed Data Protection Policy

Having a robust Data Protection Policy will allow you and your company to know the limitations of how personal data can be used and should be protected.

2. Know when Privacy and Data Protection rules KICKS IN

Basically anytime when the company collects or use an individual's personal data (including images and recordings).

Ensure that all activities involving data collection is reviewed prior to the activity commencing.

3. Be TRANSPARENT!

Let our stakeholders know why we are collecting this information and how we will use their information!

4. CONSENT is KING

Companies can use an individual's personal data in many ways as long as informed consent is given.

5. Know the LIMITS of your CONSENT

No consent. No usage. So know upfront what you need consent for because re-consenting is very difficult.

6. Be sure to know where your information is going

Internally your information may be protected but how about to third-parties that may come in contact with your data?

7. Look into whether De-identified information can be used instead?

Information which is sufficiently de-identified may not need the same information protection requirements.

8. Be responsive to queries and complaints

No in-house Privacy and Data Protection Program is perfect. However it is how we respond to complaints that could make the difference between a fine or a warning.

9. Be careful what you collect

Data must be for a business purpose and the individual must be aware that you are collecting this. You should be able to justify everything that you collect.

10. Have a designated Data Protection Officer

A Data Protection Officer can provide the business with the right guidance on how to collect and handle personal data and respond to queries or complaints in a quick and effective manner.

11. PROTECT, PROTECT, PROTECT!

Ensure that any system/database used to keep personal information is safely secure and protected from unwanted individuals. This includes anybody who has no purpose accessing this information.

12. Conduct a yearly audit of all sources of personal infomation

Annual audits ensure that any personal information being kept still has a use, is securely protected and still used within the confines of the original consent.

12 PRIVACY AND DATA PROTECTION TIPS

1. Have a detailed Privacy Policy.
2. Know when Privacy KICKS IN
3. Be Transparent
4. Consent is King
5. Know the Limits of your Consent
6. Be sure to know where your information is going to
7. Can de-identified information be used instead?
8. Be responsive to queries and complaints
9. Be careful what you collect
10. Ensure there is a Privacy Officer in place.

IF UNSURE…

If you are unsure about how compliant your organisation is with Privacy and Data Protection then there are several free tools which allow you to assess the level of maturity within your organisation.

DATA PRIVACY SCOREBOX

Your privacy compliance checklist

Based on your results, the following key action points have been identified. Please note that this non-exhaustive list has been generated automatically and that it is not a substitute for legal advice. Should you require any further assistance, please do not hesitate to contact us at dataprivacy@dlapiper.com or get in touch with one of the key contacts mentioned on the first page of this report.

Transparency

- [ ] Analyse your processing operations and verify whether your privacy notice(s) are complete and detailed enough.
- [ ] Verify regularly whether your privacy notice(s) require(s) updating.

Categories of personal data

- [ ] Verify whether any legal restrictions exist with respect to the processing of certain categories of personal data.

QUESTIONS?

Any questions you can also contact me via my email:
nyc2k3@gmail.com

THE BASICS OF ANTICORRUPTION

Cristopher Landrito, LIB
Area Compliance Officer, APAC, Takeda Pharmaceuticals (Asia Pacific) Pte. Ltd. Inc.; Former Regional Compliance Officer, APAC Group Compliance, Merck Pte. Ltd., Singapore

The Environment

- Local anti-bribery legislations
- US Foreign Corrupt Practices Act (1977)
- OECD anti-bribery convention (1997)
- UN Convention Against Corruption (2003)
- UK Bribery Act 2010

Evolving Definition of Corruption

Revised Penal Code (RPC)

Any public officer agrees to perform an act or refrains from doing something in connection with the performance of this official duties, in consideration of any offer, promise, gift or present received by such officer, personally or through the mediation of another; or accepts gifts offered by reason of his office; or any person who offers or promises or gives the gifts or presents as described

Anti-Graft and Corrupt Practices Act (ACPA)

- **accepts** or has any **member of his family accept employment** in a private enterprise which has pending official business with him during the pendency thereof or within one year after its termination

- any **relative or close personal relation** of a public official capitalizes or exploits or takes advantage of such relation by directly or indirectly requests or receives any present, gift or material or pecuniary advantage from any other person having business, transaction, application, request or contract with the government, in which such public official has to intervene

Evolving Definition of Corruption

Prevention of Corruption Act (PCA) (1960)

by himself or **by or in conjunction with any other** person **corruptly solicit or receive**, or agree to receive for himself, or for any other person; or corruptly give, promise or offer to any person whether for the benefit of that person or of another person, any **gratification** as an inducement to or reward for, or otherwise on account of **any person** doing or forbearing to do anything in respect of any matter or transaction whatsoever, actual or proposed; or any member, officer or servant of a public body doing or forbearing to do anything in respect of any matter or transaction whatsoever, actual or proposed, in which such public body is concerned

-extends to offenses committed by Singaporeans overseas

-abetment, including abetment of offenses committed overseas

Evolving Definition of Corruption

Foreign Corrupt Practices Act (FCPA) (1977)

an offer, payment, promise to pay, or authorization of the payment of any money, or offer, gift, promise to give, or authorization of the giving of anything of value to any **foreign** official, political party or its official , or a candidate for a foreign political office to influence the act or decision in an official capacity, including the decision to fail to perform official function, or to induce the use of influence with a foreign government or instrumentality to affect or influence its act or decision, to assist in obtaining or retaining business for or with, or directing business to, any person

-*including the giving to any person, knowing or having reason to know that all or a portion of the money or thing of value will be used for such corrupt purposes*

-*covers acts of domestic concerns or of issuers of securities in the US and its officer, director, employee, or agent*

-***excludes employees with ministerial or clerical duties***

Evolving Definition of Corruption

Bribery Act 2010 (UKBA)

- offer, promise or give to another person, or request, agree to receive or accept a financial or other advantage, directly or indirectly, to induce (or reward) person to perform improperly a relevant function or activity of a public nature, **connected with a business**, performed in the course of a person's employment, or by or on behalf of a body of persons, either in connection with the UK or **performed overseas**, and the person is expected to do so in good faith, impartially and/or is in a position of trust by virtue of performing it

- directly or indirectly offer, promise or give any financial or other advantage to a foreign public official, or to another person at the official's request or with its assent or acquiescence, to influence official in its capacity as such to obtain or retain business or an advantage in the conduct of business

- a **commercial organisation** may be guilty for the acts of an **associated person** with the consent or connivance of a legitimate or purported senior officer, unless it has in place **adequate procedures** designed to prevent such acts

Evolving Definition of Corruption

Act on Prevention of Improper Solicitation and Provision/Receipt of Money and Valuables (Kim Young-Ran Law) (2016)

- benefits to public officials in excess of KRW1M per instance or KRW3M aggregate from same source per year considered violation
- exceptions: meals (KRW30k), gifts (KRW50k), congratulatory or condolence money (KRW100k), including souvenirs/promotional materials intended for distribution to many unspecified persons
- corporate liability for acts of employees, subject to defense of robust corporate compliance system
- broadens “public officials” to include officials of private educational institutions, news reporters, spouses of public officials, and private persons performing public duties
- “dual punishment”

Recent Industry News

Bloomberg

Celgene Accused of Using Charities 'Scheme' to Gain Billions

August 1, 2016 – 5:00 PM SGT *Updated on* August 2, 2016 – 3:11 AM SGT

Celgene Corp. **donated** hundreds of millions of dollars to charities that help patients afford high-priced drugs for multiple myeloma and other cancers "**as part of a core business scheme** to gain billions" from U.S. taxpayers, according to allegations in federal court filings. The biotechnology giant then coordinated with the charities to ensure that Celgene's medicines were covered, violating federal law in the process, documents filed last week in a whistleblower lawsuit allege. Under a federal law known as the **anti-kickback statute**, **drugmakers are banned from giving direct co-pay help** to the country's about 40 million Medicare patients with prescription drug coverage. But they can make contributions to charities that help patients -- provided the charities are independent and there's no coordination or detailed information shared on how the drugmakers' donations are spent.

http://www.bloomberg.com/news/articles/2016-08-01/celgene-accused-of-using-charities-in-scheme-to-gain-billions

Recent Industry News

Novartis Korea executives charged with bribing doctors

Aug. 13, 2016 6:17 AM EDT

SEOUL, South Korea (AP) — Prosecutors indicted the former chief executive of the South Korean unit of Novartis and five other former and current managers over allegations they illegally paid doctors 2.6 billion won ($2.3 million) in return for prescribing the company's drugs.

. . . also indicted 28 others, including 15 doctors and six publishers of medical journals. . . According to the prosecution, Novartis' South Korean associates, . . . tried to go around the laws by funding academic events organized by publishers of medical journals, where the invited doctors allegedly received kickbacks disguised as attendance fees.

http://bigstory.ap.org/article/8dc378cf7f1a4f6e97552da6fbf29480/novartis-korea-executives-charged-bribing-doctors

Recent Industry News

Association between payments from manufacturers of pharmaceuticals to physicians and regional prescribing: cross sectional ecological study

(Published 18 August 2016)
BMJ 2016;354:i4189

"Payments to specialists and payments for **speaker fees, consulting fees, honorariums, travel costs, and non-research grants** were associated with greater regional prescribing of marketed drugs than payments to non-specialists or payments for food and beverage, gifts, or educational materials. In addition, we found that the **number of payments** within a hospital referral region was associated with greater regional prescribing of marketed drugs than dollar equivalent increases in the average value of payments.

"one additional payment in an average hospital referral region, despite a median value of only $13, was associated with nearly three months of additional prescription days filled of the marketed over a 17 month period.

"Our findings do not necessarily suggest that payments by pharmaceutical manufacturers are harmful for patient care. Patients may benefit from physicians being made aware of newly approved, effective treatments that may have fewer adverse effects, reduce the need for monitoring tests, or improve adherence. However, our findings support long voiced concerns about the potential influence of even small payments to physicians by pharmaceutical companies, such as for food and beverages.

http://www.bmj.com/content/354/bmj.i4189

Recent Industry News

U.S. SECURITIES AND EXCHANGE COMMISSION

UNITED STATES OF AMERICA
Before the
SECURITIES AND EXCHANGE COMMISSION

SECURITIES EXCHANGE ACT OF 1934
Release No. 78730 / August 30, 2016

ACCOUNTING AND AUDITING ENFORCEMENT
Release No. 3798 / August 30, 2016

ADMINISTRATIVE PROCEEDING
File No. 3-17517

In the Matter of

ASTRAZENECA PLC

Respondent.

ORDER INSTITUTING CEASE-AND-DESIST PROCEEDINGS PURSUANT TO SECTION 21C OF THE SECURITIES EXCHANGE ACT OF 1934, MAKING FINDINGS, AND IMPOSING A CEASE-AND-DESIST ORDER

"Sales and marketing staff, along with multiple levels of management at the two AZN subsidiaries [China & Russia], designed and authorized several schemes to make improper payments of **gifts, conference support, travel, cash and other benefits** to HCPs to reward or influence their purchases of AZN pharmaceuticals."

"AZ Russia employees created and maintained **charts tracking** the names of HCPs, the regions in which they practiced, their level of influence in making purchasing decisions for the respective entities where they worked and the **manner in which they could be motivated to purchase AZN products through gifts, conference support and other means**."

Recent Industry News

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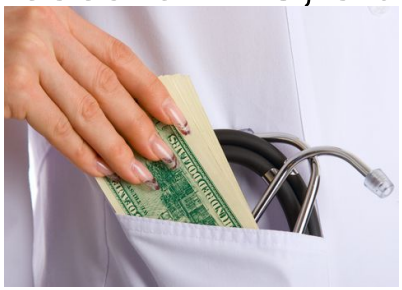
"maintained **written charts and schedules** that recorded the amount of **forecasted or actual payments** of **maintenance fees, gifts, entertainment** and other expenses . . . AZ China sales staff management approved these payments with the expectation that the HCPs would increase purchases of AZN products . . ., or favorably influence the inclusion of products on formulary or reimbursement drug listings."

"AZ China paid speaker fees to HCPs despite . . . **service contracts that were incomplete**, **containing no meeting date, venue, subject or fees** associated with the particular speaker event. In some instances, the related **speaker engagement was totally fabricated and never occurred**. . . sales and marketing team members were able to bypass formal approval procedures that required validation by a designated signatory in the company's electronic approval system.

Where Should We Focus?

Transfers of Value (ToV)

Hospitality
Fees for Services
Educational Grants
Medical Education Programs
Patient Organisation Support
Market Research
Research: IIS, studies, surveys



Sensitive GOs

Tender Committees members
Product & Site regulators
Health Economics & Pricing Authorities
Policymakers
Former Government Employees

Third Parties

- Sales and Tender intermediaries
- Vendors e.g. Event Planners, CROs, etc
- Logistics intermediaries
- Joint Ventures & Acquisitions

How Can We Mitigate Risk?

Transparency

- Standards
- Approval process
- Documentation (pre & post)
- Value transfer tracking
- Monitoring / Auditing / Compliance Assessment
- Escalation

How Can We Mitigate Risk?

Compliance Assessments

- ❑Risk assessments
- ❑Review of business plans
- ❑Pre-approvals
- ❑Regular audits

Why?

- 👍Clear business needs
- 👍Objective

Who?

- 👍Proper Selection Criteria

How much?

- 👍Modesty
- 👍Frequency
- 👍Fair Market Value
- 👍Proof of activity

Developing Effective Commercial Medical Boundaries in Interactions with HCPs

Keith M. Korenchuk, Partner
Arnold & Porter LLP
Washington DC USA

Key Issues on Medical/Commercial Interactions

- Scrutiny of relationships involving commercial and medical activities has increased worldwide as regulators and other stakeholders have become concerned about the integrity of pharmaceutical product manufacturer marketing, education, research, and publication practices
- These activities potentially implicate many international and local laws and professional standards governing product promotion, bribery and corruption, unfair competition, and research

Areas of Medical Responsibility

- Clinical research, compassionate use/expanded access, publications, and educational support strategy and planning, as well as for any other non-promotional activities with medical content
- Medical activity budgets for medical education funding, sponsorships of HCPs to attend medical or scientific meetings, charitable donations
- Medical employee and Consultant compensation and evaluations should not be tied directly to the volume of product sales or delivery of promotional messages
- Medical personnel should not report directly to commercial

Commercial Involvement in Medical Activities

- Commercial personnel should not formally or informally direct or influence medical activities, except in clearly defined circumstances
- Commercial personnel may provide high-level input in identifying areas of educational need or charitable donations and regarding research budgeting and overall priorities
- Commercial personnel may provide administrative assistance to medical projects under the supervision of medical
- Unless solicited by medical, commercial personnel should not play a direct role in soliciting, identifying, or reviewing potential individuals or institutions for medical consulting or grant-making activities

Medical Communications

- Medical communications with external parties should primarily focus on scientific, medical or educational content
- Delivery of commercial messages or materials in conjunction with medical communications is inappropriate
- Commercial personnel and Consultants should not respond to questions about unapproved uses of products or any other product; such questions should be referred to medical for appropriate follow-up
- Commercial should refer all requests for clinical, pharmacoeconomic, and other technical information from insurers/payors/government purchasers or evaluators to medical

Interactions with HCPs

- Commercial influence or control over medical consulting and grant-making activities may lead to the perception that such payments are being used improperly
- Medical consulting relationships, grants, and/or advisory board meetings should be offered only to those individuals or institutions that meet a pre-defined need, and should never be offered to enable or facilitate the delivery of a promotional message.
- Commercial should have no role in funding, convening, or selecting medical Consultants or advisors, other than in limited circumstances constituting legitimate market research or when commercial participation is justified by the objective of the discussion in accordance with the needs assessment for the activity

Clinical Research

- Inappropriate commercial influence over research activities may lead to concern among regulators and other stakeholders that a company is compromising the scientific basis for the research, compromising patient benefit, and using research as a means to reap commercial benefit or advantages from Healthcare Professionals, and thereby undermining the legitimacy of the resulting data
- Commercial should have no role in developing clinical study protocols, recruiting patients, providing experimental drugs, developing or analyzing data, retaining clinical trial Consultants or contract research organizations, or drafting clinical study reports or study publications
- All human interventional and non-interventional clinical research, as well as non-clinical research, should be overseen by the appropriate medical function without commercial input in respect of study design, unless otherwise justified by medical

Scientific Publication Activities

- Medical should be responsible for scientific publication activities, which should be independent of commercial control or influence
- Commercial control or influence over otherwise legitimate scientific publications may lead to scrutiny from regulators and other stakeholders, particularly where those publications discuss investigational products or unapproved uses of products
- Commercial influence may lead to a perception of bias, raising concerns that scientific publications are promotional in nature, lack quality and objectivity, or potentially mislead Healthcare Professionals, patients, and government evaluators
- A clear distinction should be made between bona fide scientific publications (e.g., poster presentations created by Medical personnel) and those intended to be promotional in nature (e.g., promotional monographs developed by a marketing vendor)
- Any scientific publications intended for distribution through a promotional channel (e.g., via the sales force) should be subject to internal pre-review and approval for such use
- Undisclosed financial, editorial, or technical support (ghostwriting) by any employee or vendor acting on a company's behalf should not be permitted
- Funding for scientific publication activities should come from Medical budgets, separate from Commercial control or influence
- Commercial should not be involved in the authorship, review, or approval of scientific publications or presentations

CONDUCTING EFFECTIVE THIRD-PARTY DUE DILIGENCE

17 August 2015

Katsumi KOJIMA
Corporate Officer, Country Compliance Officer Japan, Sanofi Group; Member, Code Compliance Committee, JPMA;
Member, IFPMA Code Compliance Network, Tokyo, Japan

Conducting Effective Third-party Due Diligence

- Under the U.S. FCPA, the U.K. Bribery Act, and many other local anti-corruption laws, a company may be held liable not only for the corrupt actions of its employees, but also a third party's actions when that third party acts on its behalf
- Many of the major corruption cases that have arisen in the pharma and device sectors have involved the use of local third party distributors, agents, consultants or advisers

Conducting Effective Third-party Due Diligence

- Companies can be held liable for the acts of third parties when they have:
  - actual knowledge of the corrupt acts;
  - suspicion that a bribe is likely to be paid; or
  - trying to avoid knowledge that a bribe will be paid.
- Due Diligence protects, “I really didn’t know or didn’t have reason to know….”

Conducting Effective Third-party Due Diligence

- Step 1: Evaluate the nature of the risk by type of third party
- Step 2: Fill in a questionnaire and verify the answers
- Step 3: Identify red flags
- Step 4: Mitigate red flags

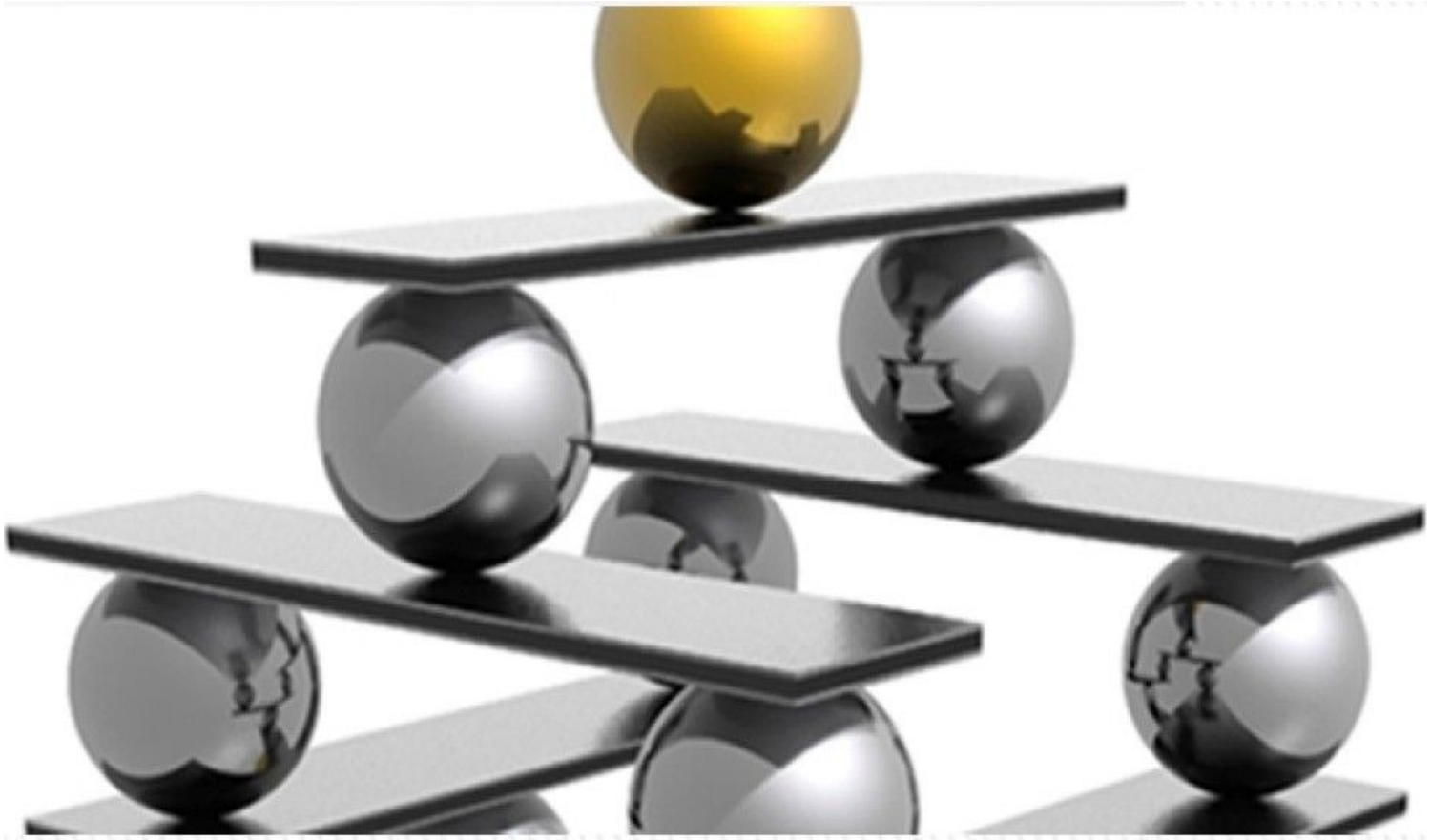
Building Effective Relationships with the Business

Aaron Yao
Cardinal Health

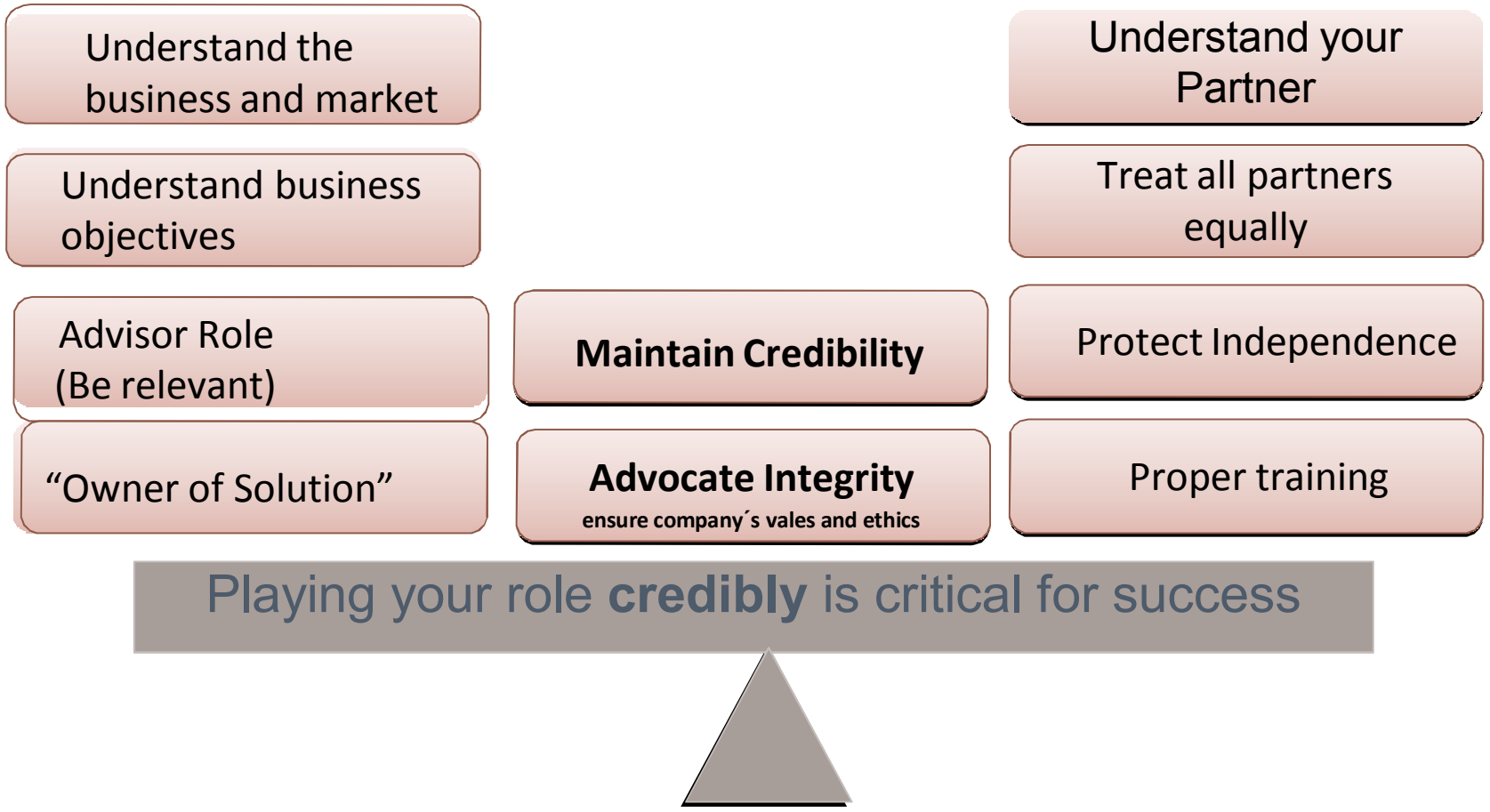
What are the Challenges Inherent to Building Effective Relationships with the Business?

How Can a Successful Compliance Leader Overcome those Challenges?

A Careful Balancing Act



A Careful Balancing Act



Enable Ethical Business Decision Making

Business Needs to:

- Own & approve the decision
- Understand the why of a decision
- Be aware of the risks/ What it would take to manage the risks
- Understand the benefits of making a good holistic decision

Ethical Decision Making Support Model:

- Clarify the dilemma: what are we deciding?
- Generate options: what's possible?
- Evaluate alternatives: what's preferred?
- Select a course: what are we going to do?
- Apply the learning: what did we learn?