# Managing Medical Device Anti-Corruption Risks

**Time: 16.15 – 17.30 pm**
**Date: May 15, 2017**

# Disclaimer

Please note that the views and opinions that will be expressed during this panel are solely those of the presenters and do not reflect the official policy, position or views of their employers.  Information has been gleaned from experiences in various settings as well as from open source data; thus, examples that may be discussed during this session are only examples and should not be attributed to any of their employers.

# Introducing the panel

**Anne-Sophie Bricca,** Deputy General Counsel, Senior Director Law and Compliance, EMEA,Terumo BCT, Brussels, Belgium; Anne-Sophie is In charge of legal and compliance Europe, Middle East and Africa. She has been on the committee that developed the Medtech code and she is currently the Vice-Chair of MedTech Europe Compliance Committee

**Ariadna Quesada, MPP,** is the International Compliance Director for DaVita Kidney Care based in Amsterdam. Previous to DaVita, Ariadna worked for Microport in Europe as a Compliance Manager Europe, Middle-East and Africa. At MicroPort she was responsible for the compliance agenda of the International business in EMEA, Latin America and Asia Pacific regions. MicroPort Orthopedics is an active member of Eucomed and Ariadna has also been involved in the development of the Medtech code.

**Michele Tagliaferri, Esq.,** *Partner, Sidley Austin LLP, Brussels, Belgium,* Michele leads the investigations and compliance team in Sidley's Brussels office. He defends multinational companies in anti-corruption enforcement actions and assists them in developing compliance programs. Before moving to Brussels, Michele worked for several years in Sidley Austin's Washington, DC office, focusing primarily on FCPA matters.

**Andy Bender, MS, MBA,** *President and Founder, Polaris, New York, NY, USA (Moderator)*

# Topics to cover (I)

- Global trends in the anti-corruption enforcement environment - Michele
  - Focus on Third Parties
  - Negotiated Resolutions of Enforcement Actions
  - Cross Border Collaboration increasing risk

- Fair market Value for services by HCP - Ariadna
  - Risks associated with inappropriate consultant agreements
  - Best practices on consultant agreements
  - Determining FMV

- Transparency reporting – Anna Sophie
  - Challenges around transparency reporting
  - How to track and what system or process to use
    - Manual vs automated
    - Challenges
  - Responses from customers re reporting?
  - Who owns this process in the company?

# Topics to cover (II)

- Challenges of the new way to sponsor HCP education through grants: Anne-Sophie
  - Definitions of Educational Grants
    - What is the purpose?
    - What is the process and who is involved in the decision making?
    - Is marketing involved in the decision making of the grant?
  - Benchmarking of budgets and requested amounts

- Anti-Corruption Compliance Developments: Michele
  - New Legislation and Guidance
  - Increasing Importance of Compliance Programs

# Audience questions

1. **Does your company have an effective compliance / whistleblowing hotline?**
    1. Yes
    2. No
2. **How many reports / year do you receive?**
    1. 0
    2. 0-10
    3. > 10
3. **Do you investigate hotline reports?**
    1. Yes
    2. no

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# Anti-Corruption Enforcement Environment

# Anti-Corruption Enforcement Environment

## *Life Sciences: Top US Enforcement Actions*

| Company | Year | DOJ Amount (millions) | SEC Amount (millions) | Total Amount (millions) |
|---|---|---|---|---|
| Teva Pharmaceuticals (Israel) | 2016 | $283 | $236 | $519 |
| Avon (US) | 2014 | $67.6 | $67.4 | $135 |
| **Johnson & Johnson (US)** | 2011 | $21.4 | $48.7 | $70.1 |
| **Bio-Rad (US)** | 2014 | $14.4 | $40.7 | $55.1 |
| **Pfizer (US)** | 2012 | $15 | $26.3 | $41.3 |
| **Eli Lilly (US)** | 2012 | -- | $29.4 | $29.4 |
| **Novartis (Switzerland)** | 2016 | -- | $25 | $25 |
| **Biomet (US)** | 2012 | $17.3 | $5.6 | $22.9 |
| **Olympus (US)** | 2016 | $22.8 | -- | $22.8 |
| **Smith & Nephew (US/UK)** | 2012 | $16.8 | $5.4 | $22.2 |
| **Analogic/BK Medical (US/Denmark)** | 2016 | $3.4 | $11.5 | $14.9 |
| Bristol-Myers Squibb (US) | 2015 | -- | $14 | $14 |
| **Stryker (US)** | 2013 | -- | $13.3 | $13.3 |
| SciClone Pharmaceuticals (US) | 2016 | -- | $12 | $12 |

# Anti-Corruption Enforcement Environment

## *Top EU Enforcement Actions*

| No. | Company | Year | Amount (millions) | Enforcement Authority |
|---|---|---|---|---|
| 1 | Rolls-Royce | 2017 | €773 | UK SFO |
| 2 | Siemens (Germany) | 2007 | €596 | Munich Public Prosecutor's Office |
| 3 | VimpelCom (Netherlands) | 2016 | €357,2 | Dutch Public Prosecution Service |
| 4 | SBM Offshore (Netherlands) | 2014 | €214 | Dutch Public Prosecution Service |
| 5 | Siemens (Greece) | 2012 | €170 | Athens Public Prosecutor's Office |
| 6 | MAN Group (Germany) | 2009 | €150.6 | Munich Public Prosecutor's Office |
| 7 | Ferrostaal (Germany) | 2011 | €149 | Munich Public Prosecutor's Office |
| 8 | Yara International (Norway) | 2014 | €43,5 | The Norwegian National Authority for Investigation and Prosecution of Economic and Environmental Crime |
| 9 | Alstom (Switzerland) | 2011 | €37,6 | The Swiss Federal Prosecutor's Office |
| 10 | Rheinmetall AG (Germany) | 2014 | €37 | Bremen Public Prosecutor's Office |

# Anti-Corruption Enforcement Environment

## *Enforcement Trends*

While the global enforcement landscape is becoming increasingly more complex, some general trends can be identified:

- **Focus on Third Parties**
  - "About 60% to 70% of the SEC's FCPA actions involve third-party intermediaries … ." (Kara N. Brockmeyer, Chief of the FCPA Unit at the SEC, December 2013)
  - Intermediaries were involved in 3 out of 4 foreign bribery enforcement actions conducted by OECD countries from 1999 to 2014 (OECD Foreign Bribery Report).
- **Negotiated Resolutions of Enforcement Actions**
  - **The use of Deferred Prosecution Agreements (DPAs) is** becoming an international enforcement trend
    - U.S.: 8 DPAs in 2016 (DOJ/SEC)
    - United Kingdom: since February 2014, three DPAs have been reached
    - Other countries are introducing DPAs: France - Law Sapin II introduced DPAs – (Dec. 9, 2016)
- **Cross-border collaboration** in anti-corruption enforcement also continues to grow
  - ✓ The largest recent settlements resulted from joint settlements:
    - *VimpelCom* (U.S. and Dutch authorities)
    - *Odebrecht/Braskem* (U.S., Brazil, and Swiss authorities)
    - *Rolls-Royce (*U.S., Brazil and UK authorities)

# Audience questions

1. Does your company have a well stablished independent body dedicated to review requests for consultant agreements?
    1. Yes
    2. No
2. Does your company count with internal resources to determine FMV?
    1. Yes
    2. No
3. Which aspects does your company consider to determine FMV?
    1. Educational credentials and specialized training
    2. Professional certifications
    3. Publications history
    4. Other professional leadership activities

# Consultancy agreements & FMV

- **Background:**

Since 1994, the OIG and DOJ have become increasingly aggressive in investigating and pursuing AKS enforcement actions related to physician consulting contracts.

In 2007, 4 major orthopedics manufacturers made headlines for being charged with conspiring to violate the AKS by entering “ sham” consulting contracts with orthopedic surgeons

# Consultancy agreements & FMV

FMV & AKS Safe Harbor & MedTech Guidelines

- Consultancy agreements should be entered only where there is a ***LEGITIMATE business need*** for services
- The number of consultants retained must not be greater than the number reasonably necessary to archive the identified need
- Selection of the consultants must be based on the business need, the service required and the qualifications of the consultants
- Consulting agreements must be documented in written.
- The hiring of the consultant must not be an inducement to purchase, lease, recommend, prescribe, use or procure the company products or services
- The remuneration of the services must be REASONABLE and REFLECT THE FMV of the services.
- The company should keep records of the services provided

# Consultancy agreements & FMV

- The remuneration paid to HCPs engaged as consultants shall reflect the fair market value for the services provided.
- It shall not be contingent upon the value of the products or services the consultants may purchase, lease or recommend.

***All payments made for the services should comply with the applicable country law, tax and other legal requirements.***

# Consultancy agreements & FMV

Term FMV is general defined as *the value in arms' length transactions, consistent with the general market value.*

“General market value” means the compensation that would be determined as the result o a bonafide bargaining between well informed partied to the agreement who are not otherwise in a position to generate business for the other party.

**Determining the FMV compensation is critical and not easy.**

*Medical device manufacturers should use internal resources or qualified independent 3rd party appraisers to determine FMV*

# Consultancy agreements & FMV

**A reliable and comprehensive valuation approach should include:**

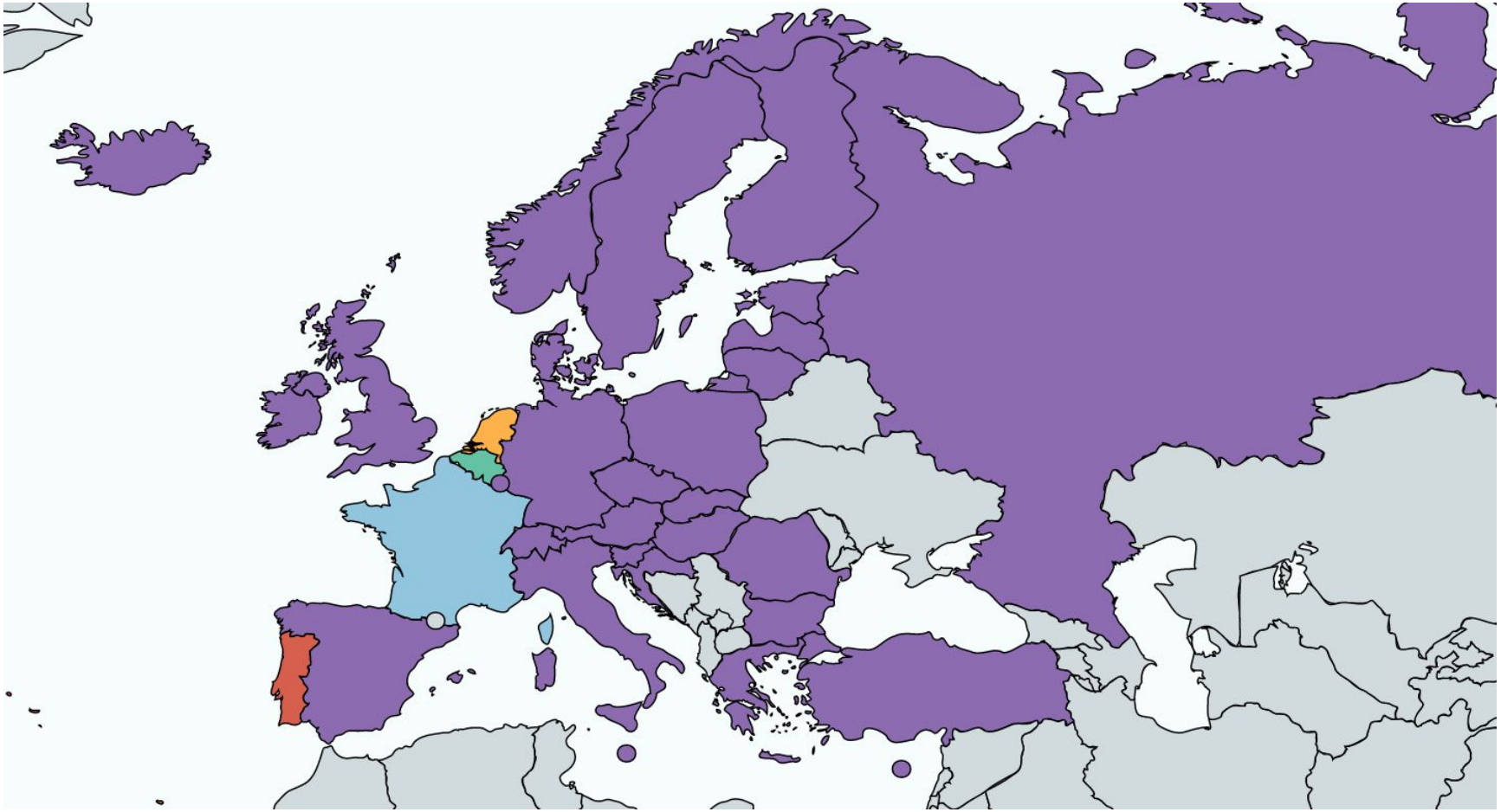
1) An evaluation methodology that analyses each parameter in an ***objective, consistent and repeatable way***
2) A FMV outcome that encompasses all relevant parameters
3) A FMV outcome that can be **supported by independent market data**

The physician compensation data from national and regional surveys can become a starting point

# Audience questions

1. Does your company track for transparency reporting purposes?
    1. Yes
    2. No
    3. We will in the future
2. Does your company have a policy or SOP for bundled discount arrangements
    1. Yes
    2. No
3. Does your company have clear definitions for grants, sponsorships and training?
    1. Yes
    2. No

# MedTech Europe Code
# Transparency geographical scope




| Firma | Zahlungsart | Betrag |
|---|---|---|
| Otsuka Pharma GmbH | Sponsoring | 215.000,00 € |
| Novartis Pharma GmbH | Sponsoring | 212.850,00 € |
| [illegible]ringer Ingelheim Pharma | Sponsoring am DGN | 96.580,00 € |
| Daiichi Sankyo Deutschland GmbH | Sponsoring | 68.060,00 € |
| Mundipharma GmbH | Sponsoring | 62.380,00 € |
| Roche Pharma AG | Sponsoring | 31.300,00 € |
| Bayer AG | Sponsoring | 11.040,00 € |
| Ipsen Pharma GmbH | Sponsoring | 9.360,00 € |
| UCB Pharma GmbH | Honorare | 2.112,25 € |
| Mundipharma GmbH | Tagungsgebühren | 100,00 € |
| | **Gesamtbetrag** | **706.782,25 €** |

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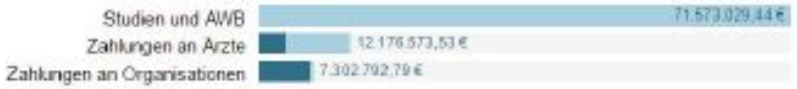
Die Zahlungen an Ärzte für Tagungsgebühren, Reisekosten, Beratungshonorare und Spesen werden personenbezogen veröffentlicht – wenn der jeweilige Arzt zustimmt. Für den Rest wird die Summe zusammengefasst angegeben. Grundsätzlich nur zusammengefasst werden die Zahlungen im Rahmen von Studien und Anwendungsbeobachtungen (AWB) veröffentlicht.




- 12 % an namentlich bekannte Empfänger
- 88 % an unbekannte Empfänger

# Educational Grants
# Definition

**Support for Third Party Organised Educational Events:**

- *Support for HCPs participation*
- *Support for event*

**Scholarships and fellowships**

**Grants for public awareness campaigns**

Can only be provided to HCOs

# Audience questions

1. **How often do you conduct risk assessments?**
    1. Never
    2. 1 per year
    3. Once every 2-3 years
2. **Do you measure the effectiveness of your ABAC compliance training?**
    1. Yes
    2. No
    3. Don’t know

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# Anti-Corruption Compliance Developments

# Anti-Corruption Compliance Developments

## *New Legislation and Guidance*

- On November 8, 2016, France passed a new anticorruption legislation, known as "**Sapin II"**
  - Sapin II has wide jurisdictional reach, makes compliance programs mandatory, introduces a new offense of influence peddling of foreign public officials and introduces DPAs as an alternative procedure to criminal prosecution

- In October 2016, International Organization for Standardization (ISO) finalized a new standard to address bribery (**ISO 37001)**
  - ISO 37001 is an international standard setting forth requirements and guidance for establishing, implementing, maintaining, reviewing and improving an anti-bribery management system. Its implementation can be certified by independent entities qualified as "certification bodies"

- In February 2016, the DOJ published its **Evaluation of Corporate Compliance Programs**, which sets forth sample questions prosecutors may ask when evaluating a compliance program in the context of a criminal investigation
  - This guidance is the latest direction released under the DOJ's "compliance initiative," which began with the hire of Hui Chen as a compliance expert in November 2015. It provides insights into how the DOJ will assess the effectiveness of compliance programs

# Anti-Corruption Compliance Developments

## *Increasing Importance of Compliance Programs*

Compliance programs increasingly serve as both preventive and defensive tools

- Certain countries include a **"compliance program" defense** (*e.g.*, UK, Italy, Spain)
  - In these jurisdictions, the company faces strict liability for failing to prevent corruption by persons associated with the company
  - Only defense against strict liability is demonstrating that the company had an adequate compliance program (or "adequate procedures") in place when the crime was committed
- In some countries, the adoption of a compliance program can serve as a **mitigating factor** (*e.g.*, U.S.)
  - Principles of Federal Prosecution Of Business Organizations
  - U.S. Sentencing Guidelines
  - FCPA Pilot Program
- In other countries, adoption of compliance program is **mandatory** (*e.g.,* France)
  - Sapin II: French companies with at least 500 employees and over 100 million euros in revenues, as well as French subsidiaries of non-French companies whose parent companies fulfill the same criteria are required to have compliance programs