

**Parallel Session 1**  
**Distributor Related Issues:**

***How Would Experts Manage this  
Distributor Compliance Scenario***

Athens, Greece

20 May 2015

11:15am – 12:30pm

# Background Information



- ACME Medical Supplies
  - U.S. listed company
  - A member of AdvaMed and applies the code globally
  - Manufacturer of medical devices and implants in humans
  - Global manufacturing footprint in 5 countries and selling into 40 countries
  - Sells products through employee sales representatives and independent distributors
  - Continually looking to expand into new international markets
  - ACME's sales representatives and distributors recommend products to physicians, who order them for surgeries on their patients
  - In the international market ACME sells its products to the distributors and they in turn sell to the medical facility where the surgery takes place for the implanted products
- ACME sales director responsible for Europe, Middle East and Africa (EMEA) has an idea to expand ACME business into Africa via its Europe distributor network

# Angola... the place to be!

- ACME Portugal Distributor - Jose Santos
  - Successful in building a business in Portugal
  - Has other business interests in Angola
    - Santos Medical Supplies
    - Family business
- Only one major surgery hospital in the Luanda, the capital city of Angola
  - Government hospital
  - Issued a tender for medical supplies
  - Want to award a 10 year contract for medical supplies
- ACME sales director considers Angola as the place to grow business... the place to be!



# Santos Medical Supplies



**What should ACME do before Santos Medical Supplies is appointed as a sub-distributor in Angola?**

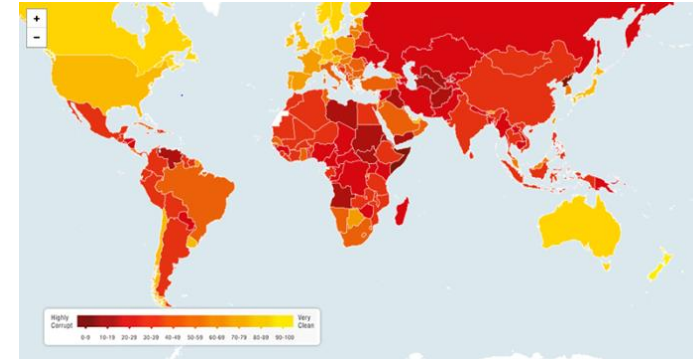


# Santos Medical Supplies



- Due Diligence Results

- Angola Corruption Perceptions Index (2014)
  - Rank 161/ 175
  - Score 19 / 100



- Santos Medical Supplies

- Business in Angola is an import / export business carrying a range of goods
- Owner is a distant relative is Jose Eduardo dos Santos, President of Angola - no business connections
- Prior issues related to customs clearances at the airport



- Luanda Hospital Tender (to close in April)

- To appoint 4 vendors - must be local businesses
- Each vendor eligible to sell to the hospital
- Product choice left with the Healthcare Professional
- Included on a country wide vendor supply list



# Santos Medical Supplies



**What should ACME do after the Due Diligence has been completed on Santos Medical Supplies - Angola?**



# Santos Medical Supplies



- Due Diligence issues being addressed
- Contract negotiations kick off
- Heated discussions between
  - ACME
  - Santos - Portugal
  - Santos - Angola
- Santos Angola staff are:
  - Not aware of the US Foreign Corrupt Practices Act
  - Not aware of AdvaMed Code of Ethics or Eucomed Code of ethical business practice
  - Pushing back on including audit rights in the agreement



# Santos Medical Supplies



**What compliance related contract conditions should ACME hold firm on and why?**





# Santos Medical Supplies



- Contract negotiations finalized and the agreements are signed
  1. ACME & Santo Portugal
  2. Santos Portugal & Santos Angola



- In April Santos Angola applies for and is registered as the product the importer and “local manufacturer” of ACME products



# Santos Medical Supplies



**What compliance training (topics and format) should be given to Santos Angola and when?**

# ACME Headquarters



- Good news spreads fast
  - Luanda Hospital closes the tender in April and Santos Angola is one of the 4 vendors selected
  - ACME Europe sales director is celebrating



- ACME Finance routinely reviews expense reports and discovers the following transactions for the Europe sales director ... and sends the details to Compliance
  - Several business trips to Angola from January to March with ACME Portugal Distributor - Jose Santos for “product installs and demonstrations”
  - Unexplained excessive charges on the ACME company credit card

# ACME Headquarters

What should ACME Compliance do?



# ACME Compliance Investigation

- ACME Expense Report Highlights
  - Several business trips to Angola prior to the Luanda Hospital tender being awarded
  - There were no product installs between January and March
  - Locations for “meetings” included
    - Beach resorts
    - Nightclubs
  - Extravagant dinners with following parties in attendance:
    - ACME Sales Director
    - Portugal Distributor - Jose Santos
    - Luanda HCPs and hospital officials
  - Gifts included wine and cigars



# ACME Headquarters

What should ACME Compliance do?



# Audit Rights

- ACME exercises its audit rights in its Distributor Agreement with Santos
- In reviewing Santos books and records it identifies a series of payments to a charitable organization called the Luanda Children's Foundation



- The Foundation is headed by an individual who is the director of the one major surgery hospital in Luanda, a government run facility

# ACME Headquarters

What should ACME Compliance do?





# Relationships and Associations

- In conducting due diligence checks, ACME Compliance determines that the Chief Operating Officer of Santos is:
  - The former Director of the Luanda Health Fund, and
  - Was involved in the Government Run Health System

# ACME Headquarters

What should ACME Compliance do?



# Product Registration

- ACME asks Santos to assist in registering a new device in country
- In working through the registration process, ACME determines that Santos has made a one-time personal payment to a local government official in an effort to expedite registration
- If Santos refused to make the payment, the process would have taken at least twice as long



# ACME Headquarters

What should ACME Compliance do?



# Customs Clearance



- A shipment of Device ABC imported into the Angola has been stopped at customs due to a problem with labeling
- Santos advises ACME that a payment to a customs officer will ensure the devices go through
- If Santos refuses to make this payment, the shipment will be delayed in customs for many months or perhaps rejected altogether

# ACME Headquarters

What should ACME Compliance do?



# Consultants

- Santos notifies ACME that it is working to break into a key account that has always used a competitor's products
- The Chief Physician of the department has significant influence over the tender specifications
  - He seeks a consulting arrangement that includes compensation at a rate of 5% of sales (as he claims the competitor has been doing),
  - He will use his influence to make the switch to ACME products



# ACME Headquarters

What should ACME Compliance do?





# Charities



- Santos is approached by the Administrator of Luanda who explains that it is remodeling the minimally invasive unit area in the hospital to provide better care
- In this respect it plans to improve the OR, walls and rooms, as well as lamps and equipment and the general appearance of the unit
- Accordingly, Luanda hospital is seeking Santos and ACME to provide a charitable contribution to purchase a painting from a local artist to be placed in the waiting area which they hope will make patients and families feel better while they wait

# ACME Headquarters

What should ACME Compliance do?



