



**The National Disclosure Summit
Washington DC
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Coordination of Compliance amongst Multiple Affiliates



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Agenda

Whether due to pending or in-progress mergers and acquisitions or the existence of independent corporate infrastructures, many companies operate as separate applicable manufacturers within the same corporate umbrella.

This session will review compliance and business considerations such as:

- Approaches to governance across applicable manufacturers
- Considerations on when to file jointly vs. independently
- When to align: How to determine how much coordination is the right amount
- Approach to shared business processes, systems and data
- Challenges with customer communications

*Disclaimer: The views of the Novartis presenter reflect a personal perspective and should not be considered an endorsement by or specific views of Novartis

Introduction to Novartis Aggregate Spend Program



- Affiliates have been acquired: Fougera by Sandoz
- Affiliates have been merged: CIBA Vision / Alcon
- Affiliates (are being) divested: “Diagnostics” from “Vaccines”

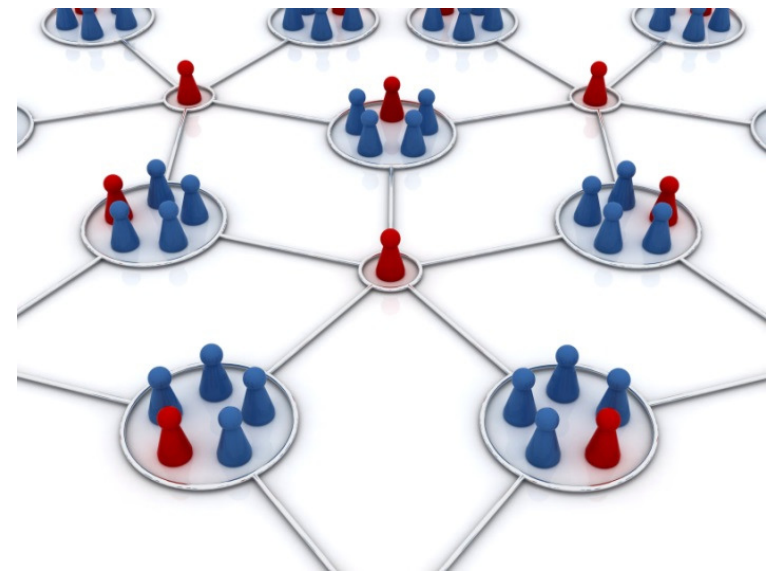
Let's Hope This is Not You!



July 21, 2010

Approaches to Governance

- Considerations
 - Role of Parent Company
 - Affiliates or “Acquisition”
 - Corporate Separateness
- Project Leadership and Evolution
 - Steering/Executive Committees
 - Cross-Affiliate Operating Leads
 - Functional Experts (Comms, Legal etc)
 - Affiliate Specific Teams



CMS Requirements for Attestation Process

- CMS Requirement:

Each report, including any subsequent corrections to a filed report, must include an attestation by the CEO, CFO, CCO, or other Officer of the applicable manufacturer that the information reported is **timely, accurate, and complete** to the best of his or her knowledge and belief.

For applicable manufacturers choosing to submit a consolidated report in accordance with paragraph (d)(1) of this section, the applicable manufacturer submitting the consolidated report must attest on behalf of itself, **in addition to each of the other applicable manufacturers** included in the consolidated report.

- Under what scenarios are your Corporate Officers willing to attest on behalf of “each of the other applicable manufacturers”?
 - Ex-US affiliate that qualifies as an Applicable Manufacturer?
 - Puerto Rico (or other territory-based) affiliate?
 - Other US corporate entities?

Alignment Reduces Risk and Creates Efficiencies

- Reputational rationale
 - Defining scope and reach
 - Establishing floors and ceilings
 - Division-specific requirements
- Operational synergies
 - People
 - Process
 - Technology / Data



Another Example Of What Not To Do



Sept 6, 2009

How to Gain Alignment

- Consistent and diverse team
- Meet regularly; in-person
- Project management: setting timelines and responsibilities
- Importance of documentation (and retention)
- Be flexible and proactive



Finding Operational Synergies: Leveraging Common Resources

- People and Processes
 - Shared centers of excellence (legal, data stewards, call centers,)
 - Shared third-party vendors
 - Standardized business practices
- Technology
 - Same instance, same software, or independent?
 - Source system commonality (e.g., all use Concur?)
 - UAT responsibilities
- Data
 - Universal customer master or AM-specific?
 - Access to aggregate spend data / cap management?

What challenges have you faced as Applicable Manufacturers?

Program Must Continually Evolves to Address New Challenges

Challenges:

- How do we handle disputes and provide clarity to customers ?
- Will the patient/customer/media understand that we are all separate companies?



Questions



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