Acquisition and Alliance Considerations in Melding Compliance Programs

November 4, 2014
Introductions

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Post – Merger, Acquisition and Alliance Considerations in Melding Compliance Programs – Base Case “A”

Assumptions:

• Publicly traded, mid-size global pharmaceutical manufacturer, acquired by large pharmaceutical manufacturer

• Acquirer is losing budget this year and CEO has stated publicly “This deal will get done.”

• Target Company has 3000 employees, with 4 approved products and robust pipeline
  • Sales force (approx. 2000), most are legacy, inherited from other acquisitions;
  • MSL team, very active in publications, CME and IIR;
  • Annual consultant agreements – cover all activity, monthly payments; and
  • Two of four approved products have high off label sales and reimbursement issues.

• Structure of existing Compliance Organization of target
  • Chief Compliance officer reporting back to General Counsel;
  • Fifth (and final) year Corporate Integrity Agreement just completed;
  • Policies were developed by outside counsel 4 years ago;
  • Auditing and Monitoring activity scaled back;
  • Increased focus on FCPA, Anti-Bribery activity;
  • Compliance budget cut by 40%;
  • Hotline in place, used mainly for HR matters; and
  • Three of six compliance personnel are “re-assigned.”
Assumptions:

- Private equity backed medical device company being acquired by a larger pharmaceutical company with a Corporate Integrity Agreement (year 3 of 5)

- Warning Letter received 3 weeks ago for suspected promotion and advertising of an unapproved product.

- Target Company size is 150 employees, revenues expected to triple over next 18 months:
  - Currently only US market focused;
  - Compliance related matters outsourced to M&A law firm;
  - Code of Conduct was launched 4 months ago, no formal training to date;
  - No formal policies, implementing SOPs or “Hot-line” exists;
  - Pre-commercial phase with product launch in 3 months;
  - Current customer-facing activities:
    - 12 Advisory Boards over the last 12 months and 3 scheduled in next 9 weeks
    - MSL’s in place for 1.5 years
    - Contract Sales Force in place for 11 months, market development activities underway
    - Speaker training for 30 speakers took place 8 weeks ago
    - Post-launch speaker programs are scheduled
# Addressing Issues identified in Pre-Merger Diligence

## Research & Development
- Clinical Trials Practices & Policies;
- Confirm existence and review of Safety Practices, Policies and Documentation;
- FDA Compliance (past and present); and
- Medical Affairs activity, specific focus on interactions with commercial organization.

## Manufacturing Organization
- Manufacturing practices (e.g.: CGMP, etc.);
- Integrity and security of supply chain; and
- Review of Warning Letters (past and present) for frequency and pattern of alleged behavior.

## Commercial Organization
- Scope and actual of extent all commercial and promotional practices;
- Review of Warning Letters (past and present) for frequency and pattern of alleged behavior;
- Review of Untitled Letters (past and present);
- Reimbursement practices (e.g.: existence of applicable Policy and governing committee, methodology, best price, etc.); and
- Consistency of executed practices with implementing Policies and Procedures.
- Review of Litigation (active and closed), specific focus on matters that are identified to be material;
- Security and Exchange Commission matters (past and present) - SOX Compliance and supporting documentation;
- Foreign Corrupt Practice Act ("FCPA") violations and communications (past and present); and
- Office of Foreign Asset Control ("OFAC") violations and communications (past and present).

## Office of General Counsel
- Review of all Policies and Implementing Procedures, creation of gap-assessment for post-closure action;
- Review of “ways of working” within the organization, specific focus on frequency and type of interactions with Commercial Organization;
- Employee population Exclusion and Debarment Check; and
- Review and gap assessment of IT-data governance/data security.
Review and track all compliance related matters raised in Pre-Merger Diligence

- How thorough is the pre-merger diligence?
- How is it tracked?
- Do you have the right level and engagement of “risk owners?”
- How is it communicated?
- When to Involve External Entities?
Enforcement Environment

Investigations:
- Identify active investigations, specific attention to those that arise to the threshold of material;
- Identify and understand closed investigations, specific focus on those deemed as being material; and
- Catalogue active and close investigation by risk area (e.g.: AKS, FCPA, OFAC, etc.), specific attention to frequency and fact pattern

Active/Closed Negotiations with Government Entity:
- Regardless of scope, identify any active/closed negotiations with a federal/state government entity;
- Request and review all correspondences;
- Ensure that all documentation is complete and up to date, specific focus on gaps in correspondences

Active/Closed Government Sanctions and Agreements:
- Establish independent in-depth understanding of the Sanction (CIA, DPA, etc.);
- Clearly delineate organizational scope of the agreement;
- Define and index extent of requirements/obligations and impacted parties (a.k.a. “covered persons”);
- Ensure that all documentation (Correspondences, Annual Report(s), etc.) is complete and up to date, specific focus on gaps in correspondences and/or inconsistent communications;
- Identify and review for thoroughness all evidence to support satisfaction of requirement/obligation and any/all certifications;
- Interview primary individual identified within the agreement as the most senior company representative;
- Interview all individuals required to certify, or sub-certify, and specific focus on depth of functional knowledge;
- Review and understand historical & current “ways of working” with the agreement holder; and (though not limited to)
- Specific to closed agreements, review all available communications and evidence to support conclusion of sanction and/or agreement.
Compliance Integration

Plan, Communicate and Execute Compliance Integration Activities:

**Create Compliance Integration Plan**
- Final Agreement
- Compliance Scope
- Plan Creation
- PMO
- Day 1 Activities

**Communicate Plan and Approach**
- Internal Compliance Leadership
- PMO
- Acquired Compliance Leadership

**Execute**
- Compliance Owners
- Policy/Training/Monitoring issues
- Compliance Standards Establishment
- Day 1 Activities

**Provide Leadership & direction**
- Own Compliance
- Internal/External