

Acquisition and Alliance Considerations in Melding Compliance Programs

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Introductions

Moderator

- Jean McKiernan, Director, PwC

Panelists

- Elizabeth Jobes, Auxilium Pharmaceuticals
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- Justin Dillon, Cegedim
- Edward Leskauskas, Ipsen Biopharmaceuticals

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.”

Post-Merger, Acquisition and Alliance: Considerations in Melding Compliance Programs - Base Case “B”

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;

Office of General Counsel

- 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 Ethics & Compliance

- 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:

