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Navigating the Re-registration and other Complexities in M&A and Carve-Outs

Too often in M&A or carve-outs, pharmaceutical executives overlook the complexities of disentangling operations and the effort required for regulatory re-registration and labeling changes. This article covers key areas for the successful re-registration, while presenting strategies to avoid common pitfalls and technical issues.

Mergers & acquisitions have been prevalent in the pharmaceutical industry as companies seek to grow and bolster their pipeline of products. In our business as compliance and quality advisors to the industry, we are seeing an upswing in carve-outs, where a parent company spins off a subsidiary or drug. More carve-outs reflect investors' desire for proven products with less regulatory risk and investment needs than developing new drugs. For sellers, carve-outs offer the opportunity to realize cash from non-strategic assets.

Whether it's M&A activity or a carve-out, there are a number of regulatory and technical business issues which we routinely see back-burnered until the deal is closed and the transition begins. A common scenario involves the new buyer acquiring an established international drug product with expectations of on-going revenue streams, oftentimes without conducting a thorough regulatory and technical due diligence. After the deal closes, the buyer's regulatory team learns that they need to re-register the facility, conduct drug listing activities and make mandatory product labeling changes. Some countries can require a complete re-approval process. These activities take time and money, and often the buyer's regulatory team lacks the bandwidth to handle these simultaneous tasks. As a result, revenues are delayed, budgets are exceeded, and the deal loses its luster.

The Solution

We argue a better path is to fully quantify the post-deal regulatory/technical activities and their associated costs as part of the due diligence process. This requires deep involvement from subject matter experts or experienced technical consultants in the early stages of the deal. When both buyer and seller have a full understanding of the scope and costs, these aspects can be factored into the deal price or negotiated into the transition services agreements (TSA's). Additionally, proactively understanding this subject may provide capitalization, escrow or other financial advantages.

Common Pitfalls – Regulatory Re-registrations

In the M&A or carve-out, the deal makers typically do not fully appreciate the re-registration workload or timeframe. This task often falls upon technical executives after the deal is signed. All too often, the acquiring firm has limited staff, minimal budget and a narrow bandwidth to take on such extensive research let alone the implementation in every country.

Some regulatory considerations:

- State licenses for drug manufacturer/distributor
- Certificates of: Authority, Free sale and Origin
- FDA notification required such as:
  – New Drug Establishment License
  – Change of Ownership of an Application
  – Transfer of IND Ownership
  – Transfer of Drug Master File (DMF) Ownership
  – Change of Drug Listing Information with Labeling
- International regulatory requirements in each country of business

Any of these can vary from a simple fax notification to a year of re-registration, product testing and new government approvals.

One remedy to avoid potential revenue delays is to outsource the product re-registration process. Compliance consultants know the county-by-country requirements and can help to minimize the delays. Ideally the compliance consultants would be brought into the acquisition process during the due diligence stage. This helps the acquiring firm anticipate potential revenue delays, quantify the costs, and identify any gaps in testing or technical data. This information can be factored into the deal price and/or the post-transition agreements. For example, the TSA may require the seller to manufacture product and/or maintain the registration for sufficient periods of time that varies by country. The buyer would then aggressively manage the re-registration process to compete the approvals prior to the expiration of the agreements.

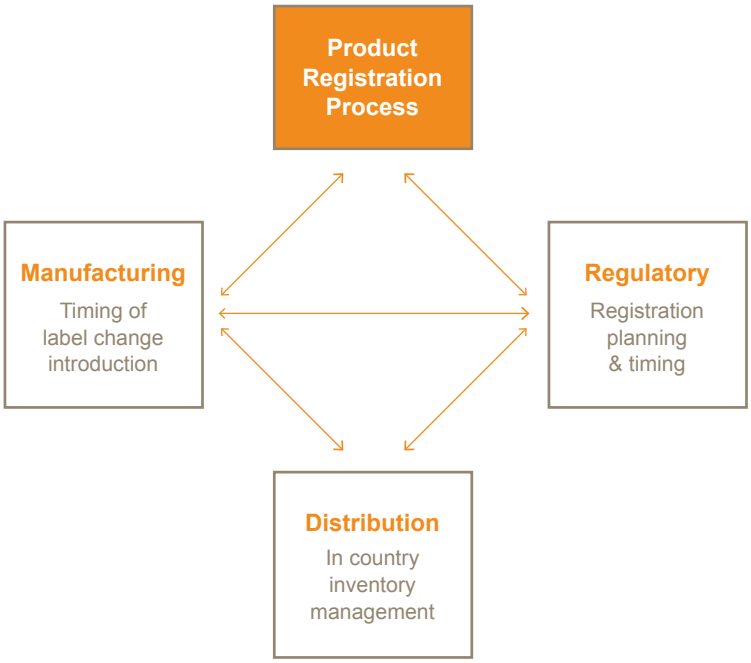
Common Pitfalls – Quality & Regulatory Systems for the Newco

Another common mistake, especially in carve-outs, is for the new company, “Newco,” to blindly adopt the legacy company’s quality and regulatory systems without regard to their smaller size or scale. While the legacy company has established quality and regulatory departments with employees to implement the procedures, the Newco finds itself with few, if any, quality/regulatory personnel and a full plate of required procedures. They are suddenly “not following their own procedures,” a risky situation during an FDA inspection (which is often triggered by a change of ownership).

Some solutions include engaging experts to right-size the new quality and regulatory systems to fit the Newco size or negotiate with the legacy company to develop the right-sized quality/regulatory system on behalf of Newco prior to the split. In all cases, Newco needs to quickly establish, and show progress towards a plan demonstrating their compliance intentions.

Common Pitfall - Cross Functional Complexities

M&A or carve-out activity is often fraught with cross functional complexity. While the acquiring regulatory team is re-registering the product and introducing new labeling into multiple manufacturing plants,



they are also responsible for assuring compliance with a myriad of spin-out tasks. This could include transferring production and managing inventory across multiple international distributors.

Introduction of newly labeled drugs and obsolescence of the old product requires coordination across manufacturing and distribution sites for each country. The central issue is whether to make more of the new label or old label product for each country. For countries with a long re-registration process, this means that old product needs to be reserved, or for the legacy company to make the drug for Newco during the transition period. Another possibility is to negotiate the transition periods with the international agencies to support the change.

All of these additional complexities take place while the technical executives must remain focused on their primary job which is getting product out the door for sale to customers.

Conclusion: Insights from the Experts

Mergers, Acquisitions and Carve-outs are complex projects that require insightful technical planning and execution to realize the deal revenue and strategic goals.

Ownership changes mandate modifications to the labeling and re-registration of the drug in every country of manufacture and distribution. A proactive, well-researched project plan that addresses the requirements of each country and coordinates cross-functional activities will save time, money and assure revenues. Given the complexity of designing and implementing the plan, experts recommend that companies determine the costs and potential revenue delays before embarking upon a M&A or carve-out. Including technical executives as a part of due diligence can help factor these costs/revenue delays into the deal price or post-deal agreements. When the technical executives are stretched thin between doing their day jobs and handling the re-registrations, expert consultants can help quantify these costs and delays, and are available to help implement the plan after the deal closes.

Case Study:

Canadian Carve-out from a Large Life Sciences Legacy Drug maker

A large life sciences company decided to carve-out one of their pharmaceutical divisions. The buyer knew that re-registration would take time and man-hours, and they recognized that the Newco would be stretched to provide the same levels of legacy regulatory, quality, IT, and manufacturing support. To solve this issue, they engaged an independent transition services manager to develop a new operations plan.

The seller used their Canadian subsidiary as a base to handle the local registration. This would not be available to Newco. Our regulatory and quality experts worked with Newco to identify a Canadian distributor and completed the steps to secure and transfer Newco's registration. We also negotiated with Health Canada an optimum transition process to avoid scrapping "old label" inventory. These steps took five months to complete, allowed Newco to exit their TSA and independently maintain their Canadian sales revenue.

Conclusions: Technical due diligence is necessary to identify subsidiary connections. These must be cleverly unraveled and re-established for successful carve-outs. Additionally, third party experts can assist with the heavy lifting that's needed to re-register and right-size technical processes for the Newco.