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Navigating the Complexities of Name Changes and Re-registration

Too often medical device manufacturers overlook the complexities of changing product names or ownership which requires regulatory re-registration and labeling changes.

Consider these common scenarios: an acquisition or carve-out occurs, and the medical device has a new manufacturer. Or the manufacturer decides to change its name as a result of restructuring. Both are common occurrences in today's rapidly changing business environment. After the dust settles on the name change, it's often up to pharmaceutical technology executives to execute the implementation plan and move the new business forward, often with little time or often with fewer resources. However, a manufacturer change or product name change requires modifications to the product labeling and regulatory re-registrations, which are increasingly complex. This article covers key steps required for successful re-registration and labeling changes while presenting strategies to avoid common pitfalls.

Requirements of Name Change

Most developed countries require a device to be registered, clearly displaying the legal manufacturer's name. Abroad, outside the European Union (EU) and US about 40% of countries require a CE (European Conformity) certificate to register the product and roughly 20% of these countries require a certificate to foreign government (CFG) or certificate of free sale from the country of manufacture in order to register the product. In the event of a company name change in the USA, the FDA requires an update to the registration per 21 CFR 807.26 and 21 CFR 807.30. In the event of a name change for devices sold in the European Union an updated CE certificate is required. All countries that have regulations concerning marketing of medical devices require some sort of notification in the event of a company name change, this can range from a simple notification to a full re-registration.

Product Labeling

A changed company name also triggers the need to update the product labeling. In the USA, the FDA requires registration within 30 days of commercial distribution of the device per 21 CFR 807. FDA 21 CFR 801 requires that the name of the manufacturer be conspicuously displayed on the product labeling. For product sold in the EU, the label must bear the name or trade name and address of the manufacturer per MDD 93/42/EEC Annex 1, 13.3. This requirement is the same for all countries that have regulations concerning medical devices.

Product labeling is a broad category covering areas including the actual product label, instructions for use, product inserts, packaging and collateral such as brochures, catalogs and other promotional vehicles.

The FDA does not require updated labeling to be submitted in order to change the company name, but clearly expects that the company will be making a good faith effort to update the label copy in a timely manner.

Requirements Beyond the USA Borders

For products sold to international markets, the requirements for each country must be researched and understood. In order to export the product, correct labeling and FDA registration is needed to obtain Certificates to Foreign Government (CFG).

While no blanket rules that apply to requirements for all export countries, all countries do require the label to match what is listed in the registration, for example, in the EU the manufacturer information on the label must match the manufacturer information listed on the CE certificate and the Declaration of Conformity.

Outside of the EU, it's not uncommon for CE and ISO certificates to be required as supporting documentation for registration. Each country has its own requirements, so it's necessary to develop an individualized approach to gathering requirements and developing an implementation plan (see table 1).

Name Change Checklist

Name Change Requires the following:

- **Updated or New registration with FDA**
- **Update Product Labeling including**
- **Instructions for Use**
- **Catalogs**
- **Brochures**
- **Research the requirements for ex-USA countries**
- **Develop a project plan for implementation in all countries**
- **Ensure the timeline is understood throughout the organization because this can delay expected revenues**
- **Get cross-functional participation and buy-in**
- **Consider external resources if the technical team lacks the bandwidth**

Table 1: Timeline and Labeling Requirements Vary by Country

Select Asian Countries	Required Documentation Elements	Typical Registration Time (Months)	Recent Registration Time (Months)
China	9	9 + 3 (Lab Test)	12 + 6 (Lab Test)
Japan	24	15	15
Singapore	13	6	6
Select Latin American Countries	**Required Documentation Elements**	**Typical Registration Time (Months)**	**Recent Registration Time (Months)**
Mexico	15	6	9
Brazil	12	9	12 must have audit
Argentina	10	6	5

Risks and Pitfalls

Risks and Pitfalls: Revenue Delays

During the merger or acquisition process, the deal makers might not fully appreciate the re-registration workload or timeframe. This task typically falls upon technical executives after the deal is signed. All too often, the acquiring firm has limited technical staff and a narrow bandwidth to take on such extensive research let alone the implementation in every country, and this oftentimes results in revenue delays. The technical executives have to bring the message about revenue delays to the management team who made the deal expecting they were buying an established revenue stream from the legacy product.

One remedy for delayed revenues is to outsource the product re-registration process. Compliance consultants typically know the county-by-country requirements, which can help to eliminate the delays (see sidebar "Potential Revenue Delays in Canada and Brazil"). Ideally the compliance consultants would be brought into the acquisition process during the due diligence stage. This helps the acquiring firm anticipate revenue delays, quantify the re-registration costs, and identify any gaps in testing or technical data, which can be factored into the deal price and/or the post-transition agreements. For example, the post-deal transition agreement might require the seller to continue manufacturing the product until the buyer can re-register the product.

Potential Revenue Delays in Canada & Brazil

Canada

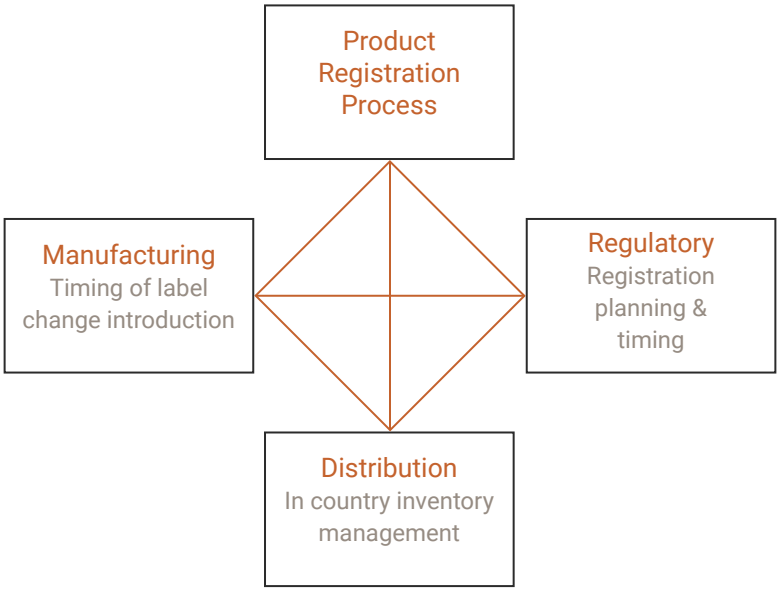
- **When the ISO certificate is updated, Health Canada must notified within 30 days**
- **If labels and ISO certificates do not match, products will not be able to pass customs**
- **Failure to meet the timeline can result in suspension of all product licenses**

Brazil

- **Brazilian customs checks for consistency between invoice and registration**
- **Updating the legal name in accordance with US Department of Commerce can trigger an issue with Brazilian customs**
- **Hence if the registration is not carefully coordinated, there is a possibility of a 7 month delay where no product can enter the country**

Cross Functional Complexities Behind Re-registrations

The reasons that drive product re-registrations are oftentimes fraught with cross functional complexity. So while the technical team is re-registering the product and introducing new labeling into multiple manufacturing plants, they're also responsible for complex tasks resulting from the acquisition. This process could include transferring production, which will trigger re-registration in most countries, managing inventory across multiple country locations, and coordinating product with multiple distributors in various countries. All this takes place while the technical executives must remain focused on their primary job functions such as getting product out the door for sale to customers.



Manufacturing Transfer

Oftentimes the manufacturing location changes as part of the merger or acquisition. Acquiring firms may see value in aggregating plants or in transferring production. The resulting changes in manufacturing location must be included in the registration process.

The added registration complexities of changing location fall upon the shoulders of technical executives who have full plates with shutting down the old facilities while onboarding new facilities. In addition, they have the challenge of introducing new labeling into the manufacturing process, and a change in location can be a trigger for facility inspections in many countries.

Distribution Challenges

Introduction of new product, and obsolescence of the old product requires coordination across manufacturing and distribution sites for each country. For countries with a long re-registration process, this means that old product needs to be reserved. Other countries, such as Spain, will allow a mixture of old/new product to be imported but will fine the company for sending the old product. For some manufacturers with multiple distributors in each export country, the coordination is very complex and falls upon the shoulders of technical personnel already engaged in other aspects of the merger or acquisition.

Some countries will allow for a transfer of registration between distributors with a short approval time, however other countries require a new or re-registration when a distributor is changed as the distributor or in country representative is the owner of the registration.

Planning is Everything

A clearly laid-out plan that coordinates the registration with the labeling revision process and any potential manufacturing site changes is essential to ensure continued market access and channel inventory for the product. The plan provides visibility for introducing the newly labeled product into the various USA and export markets.

Conclusion

Changes to the company name require modifications to the labeling and re-registration of the product in every country of distribution. It requires a well-researched project plan that addresses the requirements of each country and coordinates cross-functional activities across the company. Given the complexity of determining and implementing the plan, experts recommend that companies determine the costs and potential revenue delays before embarking upon a name change. In the case of mergers or acquisitions, it's important that technical executives are part of the due diligence team so these costs and revenue delays can be factored into the deal price. When the technical executives are stretched thin between doing their day jobs and handling the reregistration, expert consultants can help quantify these costs and delays, and are available to help implement the plan after the deal closes.

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