Selling Your FDA-Regulated Product - 11 Tips for an Effective International Distribution Agreement

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If your company is a producer of FDA-regulated products, either in the U.S. or abroad, an international distribution network can be an effective and efficient way to access the foreign or U.S. markets. Using local distributors makes good business sense—they often possess the necessary resources to best exploit a new market for a FDA-regulated product. They generally know the ins-and-outs of their territories, such as potential purchasers, customer preferences, and regulatory filing, notice, and licensing requirements. Distributors often also have effective local marketing experience, and understand local after-market service needs. However, all distribution agreements present some risks, especially for companies inexperienced in cross-border commercial contracts.

This article identifies the top 11 tips to help your company negotiate an effective distribution agreement.

1. *Perform thorough due diligence on the potential distributor*. Investigate your potential partner's reputation and capabilities. Can they deliver on their promises? Do they have experience in distributing product, both 'regular' products and FDA-regulated products?[1] What is their business reputation? Have other producers had problems with the potential distributor? Are they on solid financial footing? Could they expose your company to liability under the Foreign Corrupt Practices Act?

2. *Inventory and protect your intellectual property*. Your company should have an inventory of all of its intellectual property, including trade secrets, and how and where such property is protected. As part of the inventory, your company should understand whether its intellectual property is protected in the proposed sales territory, and what steps it should take to protect its trade secrets in that jurisdiction.

3. *Clearly define the product(s) that will be distributed*. Will modified or improved products, based on the original, automatically be included in the distribution arrangement? Does the product come in a unique package, so that your company is selling both the product and the package? Will any documentation, such as an instruction manual, be included along with the product and/or package?

4. *Accurately define territorial restrictions. Avoid generic descriptions like "North America" or "Europe."* Be specific. Also, consider whether to include language that would cover a successor state to an existing jurisdiction in the territory. Will a territorial grant to a distributor be exclusive (in that, subject to certain conditions, the company won't appoint another distributor in the territory)? Under what conditions would the exclusivity be modified or terminated, without terminating the underlying agreement? What happens if the distributor sells outside the assigned territory? In some jurisdictions, language restricting sales by a distributor outside of its assigned territory is unenforceable, so carefully draft language related to parallel imports.

5. *Consider whether to require the distributor to purchase and sell a minimum quantity of product during each year (or other time-frame) of the agreement*. A "minimum quantities"

1 As we use the term herein, a "distributor" is a third party that purchases product from the producer and then resells the product to its own customers, usually retailers or other customer-facing purchasers.

clause in a distribution agreement can incentivize a distributor to devote significant effort to product promotion and sales. Consider whether failure to meet minimum quantities will result in modification or termination of any exclusivity granted to the distributor.

6. *Will a trademark license be necessary?* If the producer has a logo or other mark, the distribution agreement should grant the distributor a limited license to use the producer's trademarks in a manner consistent with the producer's trademarks policy, and reserve all other rights. Such license should be limited to allow use of the trademarks only in connection with the promotion of the product, and should terminate at the same time as the distribution agreement.

7. *Use of documentation*. If the product includes copyrighted documentation, the distribution agreement should provide a limited license for the distributor to use the producer's copyrighted materials. It's important to note that if the distributor would need to translate the documentation into another language, the distribution agreement should be clear that the copyright in the translation vests with the producer, not the distributor. You may also want to reserve the right to review any distributor-produced advertising and promotional materials.

8. *Other intellectual property protections*. The distribution agreement should be clear that it does not grant to the distributor any of the producer's intellectual property rights, and that the producer expressly reserves such rights. The agreement should also include a commitment from the distributor to not reverse engineer the product, and to provide the producer with notice if there are other products on the market that may infringe on the producer's rights.

9. *Payment*. Consider whether to require the distributor to execute a letter of credit so that payments to the producer are secured. In addition, consider whether it is possible, or practical, for the producer to take a security interest in its products, which security interest would be released on the sale of the product to an end-user.

10. *FCPA Compliance*. U.S.-based producers can be held liable under the Foreign Corrupt Practices Act (FCPA) for the actions of its distributors. Therefore, a distribution agreement should contain language requiring the distributor to (i) affirm compliance with the FCPA; (ii) comply with the producer's FCPA compliance policy; (iii) execute annual re-affirmations of FCPA compliance; (iv) provide the producer with the right to audit the distributor's operations to determine compliance; and (v) provide the producer with the right to terminate the agreement in the event of any FCPA violation committed by the distributor.

11. *Term and termination*. How can the agreement be terminated, and what would the effect of termination be on customers? What happens to the unsold products when the agreement is terminated? Would a contract clause that eliminates termination payments to the distributor be enforced?

These are "some" of the questions—of course the specifics of a product, market or party could change some of these questions. For FDA-regulated products, remember to ensure that any required FDA-like approvals for the product are made and kept in the producer's name. The important thing is to get the distribution relationship on paper so that the parties can better manage their expectations for international markets.

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