



Strategies for managing regulatory risk with third-party distributors

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In today's global healthcare distribution market, an increasing number of medical device and in vitro diagnostic medical device (IVD) companies are aspiring to market globally. One of the main challenges these manufacturers face is how to register and distribute their products internationally. While direct distribution channels may be feasible for larger multinational corporations, third-party distribution brings its own advantages, and is becoming the norm in today's landscape.^{1,2} However, manufacturers must exercise caution by conducting adequate market, legal, and regulatory due diligence during the selection process to help ensure a successful long-term partnership with a third-party distributor.

Introduction

The global medical device market was valued at \$432 billion in 2020 and is projected to exceed \$650 billion by 2028.³ To support this growth, many device manufacturers may be seeking to expand internationally and sell their products in the global marketplace. International distribution can be challenging, however, due to regulatory complexity.

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Options for distribution

Device manufacturers seeking to expand globally generally have two options for distribution: direct distribution or use of a third-party distributor.

Direct

For many manufacturers, direct distribution initially seems to be an attractive option because it enables greater control over pricing, sales, and inventory. Direct distribution also offers an opportunity to develop an unfiltered rapport with customers, providing greater insight into their needs and the local landscape.² However, once companies begin to explore the possibility of direct distribution, they begin to realize it comes with many challenges – recruiting, hiring, and training local staff; understanding local customs, culture, and regulations; and overcoming language barriers. Moreover, hiring local staff requires setting up a legal entity in that foreign country, which can be costly with certain legal and tax implications.⁴

Successful direct distribution also involves developing a deep understanding of the complexities of the local health care system, which can vary widely from one market to another. Finally, manufacturers who are considering direct distribution must have a good grasp of local competition for their product. There may already be competing products that have a good reputation, are well-established, or have better features, which can make it difficult to gain market traction.

Given the challenges and costs associated with direct distribution, this model is typically more suited to larger organizations that have existing foreign offices, as opposed to smaller organizations that would need establish themselves in the new market.

Third-party

Smaller or mid-size organizations will likely need to rely on third-party distributors for their global expansion plans.⁴ For manufacturers who elect to go with this option, a critical factor when evaluating third-party distributors is to validate that the distributor has a history of success in the market, established contacts in the medical community, an understanding of the local regulatory requirements, and experience with the relevant therapeutic area and technology. It may also be worthwhile to confirm that the distributor has the necessary processes and infrastructure in place to attract and retain a productive sales force.²

Given that many countries can be quite bureaucratic, it is important to assess whether the distributor has access to the right decision-makers in these markets. Managing third-party distributors can be difficult, so ensuring that language is not a barrier and that requirements and expectations for communication are clear can help set up the relationship for success.

Considerations when using third-party distributors

Regulatory and quality

Many international markets require manufacturers to have local representatives in country. Some device companies opt to engage regulatory consulting companies to serve as their local representatives.⁵⁻⁷ Alternatively, the author has seen manufacturers often negotiate with their third-party distributors to absorb costs of local registration and serve as their local representative.

If the third-party distributor is serving as the local representative, it is likely that the medical device license in that country is going to be under their name. Since foreign manufacturers cannot communicate with the local regulatory authority, the distributor will need to act as the liaison, so it is important to verify that the distributor has good contacts – and is in good standing – with the local authorities. Hence, strong relationships with regulatory authorities are paramount. If the distributor does not have these relationships, the manufacturer risks getting locked out of the market, losing protection on their intellectual property, or selecting a cumbersome regulatory pathway when an easier alternative could have been possible.

From a quality standpoint, device manufacturers should ensure that any third-party distributors have an established quality system that is sufficiently robust to meet the needs of their product. As the third-party distributor will often be the first point of contact when there is a complaint or adverse event, the distributor selection process should include a careful review of the distributor's processes to ensure they have the systems in place to handle those frontline responsibilities in a timely and compliant fashion.

Differences in markets

There is no one-size-fits-all approach to navigating the international landscape. Each market has its nuances, for example some countries have private healthcare systems while others have public systems where the government may be a direct, primary buyer of medical devices. In certain countries, in the author's experience, multiple distributors may be necessary based on regional expertise. For manufacturers who are working with distributors that are leaning toward the third-party distribution model, it is important to build a clause into the contract that requires the distributor to seek the manufacturer's written approval before contracting out to any subdistributors in any other regions in that market.

Tax and pricing

Manufacturers must understand the tax structure in each country in which they intend to distribute. It is very important that the tax and pricing structure is negotiated with the distributor at the outset as product pricing is critical to the manufacturer's long-term success. Involving legal and regulatory teams in due diligence and negotiations helps ensure all issues are addressed, and the relationship is mutually acceptable.

Business and legal practices

Before initiating discussions with third-party distributors, it is essential for manufacturers to familiarize themselves with the local regulatory landscape and business practices. From a business due diligence standpoint, questions that should be asked of potential distributors include:

- What is their business structure?
- Who are their key members and board of directors?
- What is their history and reputation in the market?
- Do they have any past or pending lawsuits?
- What is the state of their financials?
- What kind of companies, products, and therapeutic areas have they worked with?
- Are they working with a competitor that manufactures similar products?
- What is their business plan and strategy?

From a regulatory perspective, distributors represent critical suppliers, especially if they will be storing product, managing product installation and servicing, and handling complaints. Any third-party distributor must be qualified under the manufacturer's existing supplier qualification process. However, the approach used for qualifying parts suppliers or contract manufacturers may not apply to distributors, so certain criteria of the qualification process may need to be modified. It is recommended to start these conversations as early as possible. Ignorance of local business practices and regulatory landscape can leave a manufacturer with limited legal recourse in the future.

Contracting

Any arrangement with a third-party distributor should include a quality agreement which can be attached as an appendix to the business contract. If the manufacturer opts to use the distributor as a local agent, it is critical for the manufacturer to understand the ramifications of having the distributor hold their medical device license. For instance, if the relationship sours in the future and the distributor refuses to nullify that license with the regulatory authority or transfer it to another distributor, the manufacturer may be blocked out of the market until that license expires. The business contract should include provisions to help mitigate this risk.

It may also be useful to consider what would happen to the distribution relationship if the manufacturer or the distributor were acquired. Businesses evolve over time and clarifying the potential impact of any changes can help to build trust and a sense of partnership.

Qualifying third-party distributors

The author has found that two types of questionnaires may be useful in the distributor qualification process: a regulatory requirement evaluation, and a distributor assessment checklist. These questionnaires can be conducted either in person or remotely.

Regulatory requirement evaluation

The regulatory requirement evaluation has a dual purpose – to help the manufacturer determine whether they should do business in that market and to clarify how well the distributor understands the local regulatory climate. The following questions are recommended for inclusion:

- What is the regulatory approval process in that country and are there accelerated pathways if the device already has approval in other markets?
- What are the timelines, requirements, and fees for registration?
- What are the local testing requirements, including requirements for electrical voltage, safety, and electromagnetic compatibility?
- Are there country-specific labeling requirements?
- What are the standards for sterilization and biocompatibility?
- What are the quality system requirements?
- What are the translation requirements?
- Who will be the owner of the medical device license, and is the license transferable?
- Is an import license required for medical devices?
- Can there be multiple distributors for the same product?
- What post-market requirements exist, if any?
- What international or local standards apply?

Comparing the distributor's responses to this questionnaire against prior experience or publicly available information will give the manufacturer insight into the competency of the distributor's regulatory team. It is also worth requesting the credentials of their in-house regulatory staff to understand their competency and experience with registering similar products in that market.

Distributor assessment

The objective of the distributor assessment is for the manufacturer to understand how qualified the distributor is in terms of the quality systems they have in place. This assessment can be formulated as a questionnaire that is either sent to the distributor to complete or used by the manufacturer as the framework for an audit.

Many distributors may have ISO 9000 or 9001 quality certification in place. The ISO 9000 family of standards outlines quality system certifications for organizations seeking to improve the quality of their products and services and to consistently meet their customer's expectations.⁸ Consequently, having this certification can be a competitive differentiator for distributors. More rarely, distributors may even have ISO 13485 certification, a quality management system standard specific to medical device processes and associated activities.⁹ Manufacturers should review the distributor's existing quality manual and SOPs, paying special attention to procedures such as document control and distribution records, which are important for traceability; complaint handling; adverse event reporting; corrective action and preventive action; product recall; and disposal.

If the country requires an import license, manufacturers should check that the distributor has one. If the medical device requires specific environmental controls for storage and transport, it is also important to ensure the distributor has the necessary storage facility and capabilities to meet those requirements. A common pitfall to avoid is the potential for product recalls or adverse events due to poor labeling translation. If the distributor will be responsible for translation, the manufacturer should require the use of certified translation companies.

Performing an audit

If the manufacturer is satisfied with the results of the regulatory requirement evaluation and distributor assessment, a reasonable next step in the distributor qualification process would be a remote, or preferably an on-site audit of their procedures and facilities, if feasible. In addition to providing validation of the distributor's responses and verification of the supplier qualification procedure, this audit presents an opportunity to build a rapport with the distributor.

Distributor performance should be re-assessed on an on-going basis, as defined by the manufacturer's supplier qualification procedures.

Special regional considerations

Certain geographic regions have specific regulatory requirements for distributors, and it is incumbent upon the manufacturer to understand and navigate these regulations. Examples of two such markets that have specific requirements for medical device distributors are included below.

European Union

The EU Medical Device Regulation (MDR) 2017/745 and the In Vitro Diagnostic Medical Device Regulation (IVDR) 2017/746 outline obligations of both distributors and importers as Economic Operators.^{10,11} Article 14 of the MDR/IVDR stipulates that, before placing a device on the market, distributors must verify that the device has been CE marked and supplied with both labeling and unique device identifier information. The instructions for use and product labels must be available in the official language of the country in which the product is sold. Under MDR and IVDR, distributors are also responsible for ensuring that storage and transport requirements comply with the conditions set out by the manufacturer. Distributors shall keep a register of complaints and ensure that any complaints are immediately forwarded to the manufacturer, and corrective actions are reported to member states.^{10,11} Both MDR and IVDR require distributors to inform the authorities if they suspect a product is falsified or poses a serious risk.^{12,13}

Article 13 of the MDR and IVDR stipulates additional requirements for importers, such as identifying themselves on labeling, and registering in the European Databank on Medical Devices.^{10,11}

Health Canada

Distributors and importers in Canada need a medical device establishment license (MDEL), a license issued to Class I manufacturers, importers, and

distributors of all device classes to permit them to import or distribute a medical device in Canada. This license can only be obtained through submitting an MDEL application to Health Canada in which the entity makes a formal attestation that they have documented procedures in place for:¹⁴

- Distributor records
- Complaint handling
- Recalls
- Mandatory problem reporting
- Handling, storage, delivery, and installation (if applicable)
- Installation
- Corrective action
- Servicing (if applicable)

Distributors and importers are subject to Health Canada audits as that agency has a compliance branch focused exclusively on auditing companies that have MDELs. The agency performs routine audits, above and beyond the medical device single audit program. MDEL is subject to annual renewal before April 1 of each year.¹⁵

In Canada, the distributor or importer also has joint responsibility with the manufacturer for filing recalls and managing problem reports on device products.

Key components of the quality agreement

The quality agreement between a manufacturer and third party should include several key elements. First, the agreement should describe registration related responsibilities, in other words, who obtains and who owns the regulatory approvals. It should also delineate the distributor's responsibility to liaise with the relevant regulatory authorities on the foreign manufacturer's behalf. If the distributor has or intends to produce any promotional material, the agreement should include a clause that requires the manufacturer's review and written approval of that material prior to use in the market. This helps limit the risk of unsupported claims.

Quality agreements should also include a clause that requires the distributor to forward any complaints to the manufacturer within a specified timeframe, often 24 hours. Vigilance and disposal procedures, as well as packaging, warehousing, and servicing responsibilities, and timing for retention of distribution records should be outlined where applicable. The agreement should also allow the manufacturer and any applicable regulatory authorities to audit the distributor on an on-going basis.

Quality agreements must be customized based on market specific requirements. For instance, for distributors in the EU, where MDR and IVDR apply, the agreement should define the specific Article 13 and 14 obligations for the importer, and distributor, where applicable. Existing EU distributor agreements under the directives should be renewed and updated to ensure that the EU MDR/IVDR requirements are met.^{10,11}

For manufacturers, engaging quality and regulatory staff in the review of quality agreements during the process of signing a business contract with each distributor is key.

Key takeaways

For manufacturers who are considering the use of third-party distributors, it is essential to create and implement a rigorous internal process for distribution qualification and selection. It is also important to develop a thorough understanding of the local market, healthcare system, regulatory landscape, and international product distribution process. Markets vary widely, so a one-size-fits-all approach may not work across all distributors. Having the flexibility to apply custom approaches to distribution arrangements minimizes regulatory risk and optimizes the likelihood of commercial success.

About the author

Maham Ansari, MS, RAC, is director, IVD regulatory & quality consulting at Precision for Medicine. She has more than 15 years of global regulatory leadership experience in the medical device and in vitro diagnostics industry. Her expertise includes full life cycle management of highly complex medical devices and IVDs from all stages of product development, execution of global regulatory strategies, and leading postmarket surveillance activities. She is well versed in leading interactions with the US Food and Drug Administration, Health Canada, EU notified bodies, and in authoring and project managing complex submissions. Ansari also has a proven track record of registering complex products in emerging markets within Latin America, Middle East, and Asia Pacific. She has a BAsC degree in chemical engineering from the University of Toronto and a master's in bioscience regulatory affairs from Johns Hopkins University, Baltimore. She is also an active RAPS member and holds a Regulatory Affairs Certification. She can be contacted at maham.ansari@precisionformedicine.com

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