

DISTRIBUTOR GUIDEBOOK

FOR ISRAELI DEVICE MANUFACTURERS

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INTRODUCTION

Entering a new market is a significant decision for a company. To effectively enter a new market, a company is required to familiarize itself with the target market – opportunities, challenges, regulations, and many other relevant aspects.

In many situations, collaborating with a dedicated distribution partner is the most effective strategy for gaining a foothold in the target market. This is particularly true for medical devices.

Distributors can offer many benefits for promoting Israeli medical devices in international locations, but at the same time, there are many different types of distribution partners. Some focus on distinct clinical fields (like oncology or orthopedics), others specialize in specific product categories (such as surgical equipment or diagnostic tools), and others focus on specific end users (like hospitals or clinics).

Therefore, choosing a distributor that is appropriate for the company is a critical process.

This **GUIDEBOOK** is intended to help assess which is the relevant distributor for the promotion of the Israeli company in the target market.

There are two main users of this guidebook, but it is open for widespread use for the benefit of any type of Israeli organization.

1. **Israeli device manufacturers** can use this as a baseline to assess which distributors can be most effective in their international expansion and sales.
2. **Israeli governmental representatives** in international locations can use this guidebook to help promote Israeli Device Manufactures and support the Israeli company in selecting the right distributor.

This DISTRIBUTOR GUIDEBOOK is organized as follows:

- Initial Considerations – Getting Started
- Minimum Requirements – Must Haves
- Additional Requirements – Nice to Haves

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GETTING STARTED

Prior to entering a new market and engaging with a distribution partner, it is important to carry out a preparatory assessment. Israeli device manufacturers, as well as governmental representatives, should dedicate time to familiarize themselves with the target market. This should include a market assessment of which countries or regions have the highest need for the product, mapping out and profiling existing distributors in the target market, and preparing any relevant documentation for engagement with a distributor.

This guidebook assumes initial preparation has been completed. A separate manual for the initial steps will be made available in the coming months.

MINIMUM REQUIREMENTS – MUST HAVES

The following criteria are minimum requirements for selecting distributors. Israeli device manufacturers and Israeli governmental representatives can potentially work together, if they want, to assess the relevancy of the distributor.

Previous Experience:

- Recommended minimum of 3 years' experience in medical device distribution in the targeted country/region, specifically:
 - Launching, managing, and growing medical devices in the target market.
 - Navigating the complexity of the healthcare system in the target market
- It is important to assess previous experience with successful distribution of high-tech medical equipment in the target market
 - *Note: Can specify here experience in a particular clinical use, medical setting, or defined customer base*

Operational Aspects:

- The distributor must be a recognized legal entity in the target market,
- The distributor must be certified to operate as medical device distributor
- In certain cases, the distributor must also have certification to operate as an importer.
- Assessment that the distributor has dedicated staff and resources to see through distribution efforts in the locality.
- Review operational professionalism, including
 - Upholding regulatory standards in marketing and sales.
 - Ensuring transparency and relevant documentation in all transactions with clients, customers and end-users.
 - Avoiding practices that could compromise patient safety, data privacy, or professional standing of the product.
- Recommended language proficiency including:
 - Fluent English across all communication channels, including documentation.
 - Ability to understand and interpret technical documentation, legal agreements, and marketing materials.

- Capable of conducting professional presentations and training sessions in English for international audiences.
- Distributor should demonstrate familiarity with local tariffs, customs, trade agreements, or tax considerations that can potentially impact the product
 - Including familiarity with documentation necessary for customs, labeling, and packaging requirements
- Review distributor needs and requirements pertaining to distributor fees, exclusivity, termination clauses, liabilities, or any other pertinent matter

Sales Capabilities:

- A distributor should demonstrate well established and active connections with relevant customers
 - Including: End users, decision makers, key executives who have influence and financial resources to execute transactions
 - Including KOLs who can influence decision makers
 - *Note: Can specify here a particular clinical use, medical setting, or defined customer base*
- Ideally distributor should have extensive pipeline of additional customers relevant to the specific product
- Additionally, distributor should show infrastructure and strategy for outreach to expand pipeline beyond existing network

Marketing Capabilities:

- The distributor should demonstrate a wide scope of potential customers, customized to the product and the product offering. This may include:
 - Public and private hospitals, clinics, and outpatient centers.
 - Home care markets, community care, clinics, outpatient care centers, ambulatory service centers
 - Any other provider organizations that may express interest in the product
 - Any other strategic, corporate, or industry organizations that may be relevant for the product.
- What is the scope of marketing resources, including strategy, staff and budget, to support product promotion as customized to the needs of the product
 - This information should appear in the contract between the distributor and the device manufacturer

- Distributor should provide a description of marketing efforts and go-to-market strategy, defined to the needs of the product. This may potentially include:
 - Customer segmentation and outreach
 - Utilization of digital marketing mechanisms as need be
 - Exhibition/conference participation
 - Messaging and product promotion

Technological Capability:

- The distributor must be familiar with technical aspects of the product and be able to demonstrate how the technical aspects are relevant to potential customers and can be implemented and adapted to potential customers. Ability to assess technical needs and capabilities of potential customers as it pertains to onboarding and implementation of the product.

Management Capability:

- Distributor should demonstrate capability to train customers on using the product, which may require
 - Infrastructure, staff, and resources required to deliver professional training programs to healthcare professionals and end-users
 - On-site workshops and remote training sessions as needed
 - Distribution of user-friendly guides and multilingual training videos.
 - Ability to adapt training materials to different customer needs
- Proven capability to integrate the product into customers side, including troubleshooting hardware and software issues.
- Proven ability to successfully integrate upgrades and/or enhancements of the product to the client.

Regulatory Capability:

- Distributor needs to have familiarity with local regulatory requirements as it pertains to the product, including product registration and compliance with local standards.
- Ability to assist with helping product reach local regulatory/compliance standards efficiently.

- Capability to handle regulatory documentation if needed, ensuring timely and accurate submissions on behalf of the product

Post-Market and After-Sales Capability

- Defined after-sales capabilities, including:
 - Providing technical support and troubleshooting guidance.
 - Managing product warranties and replacements efficiently.
 - Conducting periodic follow-ups with customers to ensure satisfaction and retention.
 - Incidence reporting and corrective actions

Financial Stability

- Financial stability to support:
 - Initial and ongoing inventory requirements
 - Marketing campaigns and promotional activities.
 - Skilled personnel for technical and sales support.
- Ability to sustain operations during economic fluctuations or delays in regulatory approvals.
- Review if the distributor has a strategic plan for periods of decreased demand and how it will affect the product and the relationship with the manufacturer.

Administrative Capability

- Quality Assurance and Audit Readiness
 - Quality Management Systems: Distributors must maintain robust quality assurance systems that comply with QMS standards (for example ISO 13485 or equivalent).
- Audit Preparedness and Compliance
 - Organized record keeping and readiness for audits or inspections by regulatory authorities in the target market
 - Implementing feedback from audits and inspections to maintain compliance and operational efficiency.
- Inventory Management System
 - Implementation of an efficient inventory management, logistics, and distribution system to:

- Maintain optimal stock levels to avoid shortages or overstocking.
- Provide real-time inventory updates to management team
- Fulfill urgent orders promptly to support customer needs.
- Working with product management to maintain deliverables

Important: all the points above should appear in a legally binding contract between the distributor and the device manufacturer.

It is strongly recommended that the Israeli device manufacturer, or the Israeli governmental representative in an international location, request at least three references from the distributor. All of the points above should be reviewed with reference.

ADDITIONAL REQUIRMENTS – NICE TO HAVE

The following criteria are additional considerations that may be relevant to either the target market or the Israeli device manufacturer and should be reviewed on a case-by-case basis depending on the situation.

Prior Experience with Israeli Companies

- Distributors with experience working with Israeli companies may be preferred due to:
 - Familiarity with Israeli business culture and regulatory frameworks.
 - Ease of reviewing distributor qualifications with an Israeli reference

Commitment to Compliance and Ethics

- Certain international locations may require demonstration of a commitment to ethical business practices
 - May also include commitment to patient safety and liability

Environmental Compliance

- Certain international locations may require demonstration of commitment to environmental compliance, which may include
 - Sustainable Operations: Adhering to environmental regulations for medical devices, including disposal and recycling programs, as needed by region. Examples may include:
 - Compliance with WEEE (Waste Electrical and Electronic Equipment) directives in Europe.
 - RoHS (Restriction of Hazardous Substances) compliance to limit hazardous materials.

Reputation and Customer Satisfaction

- Request a list of previous customers and conduct screening calls to gather feedback on the distributor

Long term goals

- It is possible to also explore longer term relationships with the distributor as well. Longer term contracts typically give more favorable conditions to the device manufactures

Regulator Relationships

- In some situations, national, regional, or local regulatory bodies have an impact on the market, and it may be beneficial to understand if the distributor has the necessary relationships with regulatory agencies.