Valued partner

Contracting out market access activities frees life sciences companies up to do what they do best.

WORDS BY *Sathyanarayanan Krishnamurthy*

The world of life sciences is always evolving; so is the need for medicinal product/ medical device manufacturers to expand their operations globally. Merely inventing a pathbreaking medicine or a device won't fulfil the purpose of life sciences companies. They must ensure that the drug/device reaches the end-user in the quickest and safest possible way. They should create real value for patients in need. But what if the patient segments are distributed far and beyond the origin of manufacturing? In such cases, it is essential to access the markets where the potential patient segment exists. However, market access needs to be carried out with caution to increase the scope of the business and to serve the purpose of life sciences.

To gain a competitive advantage in the target market, companies should focus on well-defined approaches that reflect local needs, not only from the product perspective, but also from the regulatory point of view. The strategy varies from company to company, but with the same underlying goal – successful market access.

In the field of life sciences, the market access strategy must align with that of the target market's guidelines and regulations for successful product compliance. There are a few key factors that companies should focus on:

- An intelligence-driven regional market approach
- Appointing local teams inclusive of qualified persons or authorised representatives
- Establishing better contacts with local/ regional health authorities
- Analysing product and organisational readiness.

Though a winning market access strategy must focus on all the points mentioned above, it appears to be of viable benefit only when applied to large manufacturers. Small or mid-sized companies do not, at times, possess sufficient in-house capabilities to access the markets beyond their reach. Even some larger manufacturers feel that they should invest much of their time and effort in new inventions rather than focusing on market access procedural setbacks. Therefore they must opt for third-party support, or in simple terms, contract out their market access activities.

> "Partnering enables companies to ensure that the product reaches the market on time by lowering overall business risk"

OUTSOURCING BENEFITS

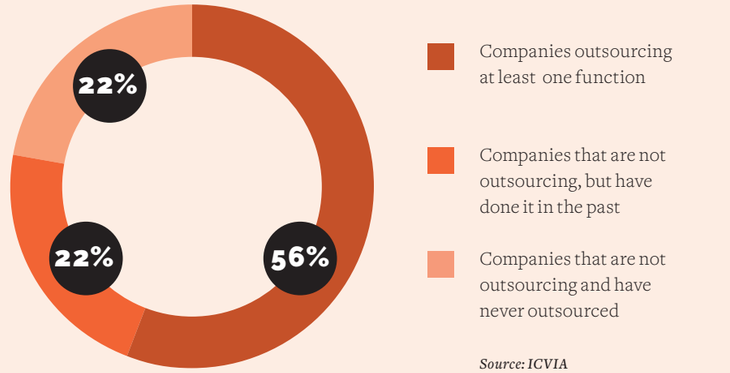
In the past, partnering in the field of life sciences was considered a risky approach, given concerns about clinical data safety, patent transparency, and so on. However, the global life sciences industry is evolving at a rapid pace and becoming more dynamic. The challenges, such as changing regulations and market dynamics, make it difficult for companies to obtain the necessary approvals in time. To ensure that the compliance is taken care of, companies often subcontract their regulatory activities to regional experts/service providers such as regulatory affairs specialists, regulatory intelligence (RI) providers, and life sciences regulatory experts. The benefits of this approach include:

- Less time to market: Partnering with regional compliance experts can drastically reduce the go-to-market time for the manufacturers. Regional experts' knowledge of local regulatory procedures saves time spent on creating, reviewing and submitting the dossiers, leading to increased chances of quick approvals and early entry to market.
- Reduced costs: Partnering with compliance experts provides companies with significant cost advantages. Instead of establishing an exclusive local operational hub and recruiting an in-house team which might require specialised training, companies can choose expert consultants who can handle local operations individually at a considerably lower cost.
- Risk management: Compliance or regulatory partners are highly skilled experts and are well versed in the conditions of the target markets. It is easier for them to mitigate the risks associated with the market access strategy and overcome any unwanted challenges. Partnering enables companies to ensure that the product reaches the market on time by lowering overall business risk.

THE CURRENT SCENARIO

Regulatory partnering in life sciences is growing fast; many companies partner with third-party compliance experts to ensure optimum results. The global pharmaceutical regulatory affairs partnering industry was valued at USD 5.7 billion in 2018 and is expected to grow at a CAGR of 11.9%. [1]The practice of regulatory partnering has proved beneficial for life sciences companies as it allows them to focus on key areas of operation, thereby improving efficiency.

REGULATORY PARTNERING



Source: ICVIA

According to research from IQVIA[2], most life sciences companies are in favor of regulatory partnering. Almost 56% of the pharma companies are partnering with compliance experts for one or the other regulatory activities. The majority of the manufacturers and new market enthusiasts say that regulatory partnering streamlines all of their procedural activities and ensures quick market access with lower cost and a managed risk profile. However, caution is needed while choosing the right partnering model.

PARTNERING AND OPERATING MODELS

As health authority guidelines and requirements evolve, the challenges pertaining to market access tend to change. Companies therefore need to choose the correct operational model based on their requirements. Models that companies generally adopt to address the challenges include:

1. Functional Service Provider (FSP) model: The FSP model offers companies the freedom to pick and choose the regulatory functions that they wish to outsource to a third party. The majority of big life sciences companies opt for this model, as it provides the flexibility of resources while reducing cost and maintaining quality.
2. End-to-End model: Since small-sized companies might not have specialised resources to autonomously carry out all functions, they choose the end-to-end subcontract model.
3. Hybrid model: Mid-sized companies often opt for a hybrid model to manage their regulatory activities. They use the FSP model to understand the dynamics of the domestic market, and the end-to-end model to ensure successful market entry to international markets.

Regulatory partnering is a beneficial factor for compliant market access. It is time that companies shifted from traditional market access strategies. With the plethora of operating models available, regulatory constraints can easily be overridden, with a special focus on evaluating the right partner. It is important that companies ensure that the prospective partner has the right regulatory talent, intelligence, flexibility, and fits the bill of delivery models and the high-end technical excellence that suits the sub mission's needs.

Sathyanarayanan Krishnamurthy is Vice President - Regulatory Operations at Freyr Solutions. Go to www. freyrsolutions.com

[1]https://www.grandviewresearch.com/industry-analysis/biotechnology-pharmaceutical-services-outsourcing-market | [2]https://www.iqvia.com/-/media/quintilesims/pdfs/seizing-the-potential-of-commercial-outsourcing-in-the-pharmaceutical-sector.pdf