IPI Speaks with PharmaLex's Local Affiliate Services Lead on the Rapidly Changing Global Market

Q: Can we start with some insights as to why the Local Affiliate Services solution was established and what its overarching objectives are?

A: There is rising demand from our clients for services at the local level to manage mandatory activities that are normally handled by their affiliates. The need was initially greatest at large organisations, which were looking to streamline the business and focus on their strategic development projects. To achieve that, they needed support to ensure they met their local compliance obligations, especially for their mature products.

There is now a growing trend amongst mid-sized companies wishing to expand into new geographic regions, but without having to invest in the setup of the required local roles. As an example, a Japanese client that was launching products in Europe needed local affiliate support to meet their obligations in various EU markets but decided not to invest in hiring their own people in each country because they would not have enough work for a full-time role.

We have also found that many clients who have been working with a diverse set of local services providers welcome that PharmaLex is in a position to offer them consolidation and all the support they need.

Q: A lot is said about the challenges companies have with managing compliance requirements at the affiliate level. Why is a more all-encompassing approach to managing the local affiliate important?

A: Compliance requirements often relate to more than one country, for example, the update and controlled implementation of a new side effect in a leaflet, an update to packaging material or the reporting of cases. If such activities are handled by several service providers, the sponsor company would have to oversee the status of each activity for every concerned country. Having an all-encompassing approach with a program leader and function-related workstream leads at one service provider minimises oversight and control for the client company, while giving them confidence and ensuring compliance.

Another important consideration is the growth in mergers and acquisitions or portfolio acquisitions, which can result in short-term joint ventures. These require quick setup of local mandatory and operational roles.

Sometimes, contracts preclude having these joint venture activities handled by either company involved in the joint venture, so a third party needs to take over local tasks. These might include changes in packaging materials and ensuring the right information is included to facilitate the transfer of the product/s or venture.

Q: Conversely, what are the biggest challenges and limitations that local affiliate resources face in a rapidly changing regulatory environment?

A: At the local level, you need to comply with national regulations and maintain a trusted relationship with your local health authorities, ensuring that established products remain compliant.

On the other hand, you are striving to ensure you follow headquarter guidance and meet the work schedule, particularly on priority and strategic development activities.

Also, the follow-up of new local requirements needs to be fed back to headquarters to be included in the overall global strategy and plan.

This situation of different tasks and priorities may be a stretch in terms of workload, availability, adequate response times and cost for the local staff. However, this local work is of major importance to keep the business steady and growing, while meeting compliance requirements.

Q: What do companies need to do to both meet their local affiliate compliance requirements while retaining a single, unified global perspective? (Is it even possible?)

As previously mentioned, the local affiliate needs to comply with local regulations and maintain a trusted relationship with the local health authorities to keep established products on the market. These demands may prevent them from having the time to focus on the company's strategic development projects.

In order to both meet compliance requirements and support the business objectives, it may make sense to separate these responsibilities through an external partner to support and manage daily routine tasks.

The added benefit of this is it allows companies to take advantage of faster, more streamlined processes. While local affiliates are highly professional, there can often be resistance to changes to established ways of working. This is at odds with a global push to get products to market faster and at less cost, both to the benefit of the company and to patients.

Q: What are the biggest limitations facing the local affiliate model and how can they be mitigated?

A: Especially for smaller or mid-size companies expanding their territories, it may be very cost intensive to install a full affiliate model with all the locally required functions and tasks, for example a designated person for health authority communication, the screening of local literature, the handling of complaints or a 24/7 contact, sometimes even before the launch of their product and having actual revenue.

For large pharma companies, on the other hand, a focus on routine tasks can make it hard for affiliates to concentrate on strategic work or require them to bring in additional resources at added cost.

Sometimes there is also no need for a full-time employee, but there is still a requirement to have a local person with specific qualifications to manage certain activities, such as pharmacovigilance obligations. Hiring someone with the required education and background for just 20 hours a month can be extremely difficult, if not impossible, especially in markets where there is competition for a limited number of professionals. However, a service provider can handle those tasks efficiently and more cost effectively because those local staff members manage compliance activities for several clients.

Q: Are there cultural barriers holding companies back from improving the collaboration between the local affiliate and headquarters? And, if so, what are these?

A: Open reflection on long-established processes and the acknowledgement that some practices do not work efficiently any longer may be difficult in certain cultures, preventing the improvement and streamlining of activities.

In addition, local staff are often so busy with their daily tasks and routine that they cannot see possibilities for reducing burden and concentrating on strategic tasks. This is accompanied by the fear of losing control if they don't manage everything themselves.

Bringing in an external perspective can break such obstacles and lead to more efficient ways of working.

When implementing local affiliate services in one region for a large pharmaceutical client, we have encountered resistance to adopting new, more streamlined procedures. At the same time, due to cultural nuances, the affiliate has been uncomfortable pushing back. With careful management, it was possible to gain confidence, openly address concerns and finally have a willingness to adapt.

Q: What role can/does technology play both in creating more barriers between HQ and affiliate and, conversely, driving a more harmonized approach?

A: It is important to consider both the advantages and potential barriers that technology offers. There is certainly huge potential for harmonisation. For example, technology enables real-time collaboration, allowing headquarters and affiliates to work together on shared platforms, such as project management systems or document collaboration tools. This facilitates faster decision-making, enhances efficiency, and promotes a sense of unity among teams.

Technology can also offer substantial support and access to resources, for example, by screening intelligence developments using an automated approach and offering easy access to training materials and best practices. This allows affiliates to tap into headquarter expertise and leverage shared resources, fostering a harmonized approach in terms of processes, quality standards, and regulatory compliance. It also allows headquarters to anticipate affiliate needs and consider them early in the planning process.

At the same time, there is also a risk of information overload, so headquarters needs to be careful not to flood affiliates with excessive data and instructions, as this can hinder effective decision-making and cause confusion, and potentially even lead to inconsistencies and mistakes in interpreting data.

An overreliance on technology for communication can also lead to misunderstandings or misinterpretations. Where there are cultural and language barriers, technology-mediated communication can make it challenging for HQ and affiliates from different regions or countries to understand each other's perspectives and work together seamlessly.

Q: What does the term Glocal mean to you, and how can its vision be realized?

A: Glocal for me is a PharmaLex attitude: we think globally and holistically. Most of us come from the pharma industry or health authorities and understand the responsibilities of central functions. On the other hand, we respect and recognise the importance of the local national requirements and of having adequate representation and responsibility on the ground. It means having a global vision supported by local people, including having native language speakers who have specific local knowledge and connections.

With our own affiliates or team members, as well as with qualified local consultants and partners, our professionals around the world have relationships with the regulators and, where relevant, can attend training sessions provided by the regulators and give input to local or regional industry trade associations.

They are able, by way of example, to compile a regulatory dossier according to local requirements, to follow up the process with the local health authority, or to take the responsibility of a national contact person for pharmacovigilance.

At PharmaLex, because we work in many regions, with many different companies and products, we tend to attract highly motivated employees who are eager to take on new opportunities and apply different skill sets.

Q: PharmaLex's Local Affiliate Services solution seeks to help companies navigate a more complex global regulatory environment through a tailored model. What does that look like in practice and why is it important?

A: At PharmaLex, we listen to the needs of our clients. We never apply a standardised one-size-fits-all model of support. Instead, we develop a setup that is best for the client and agree on a model for collaboration, reporting and issue escalation together. Depending on the scope of activities, we may have a program manager as the primary point of contact for the client, appoint specific workstream leads and regional hub teams, or, in some cases, have a very lean collaboration structure where the client can work directly with our local experts, without additional overlay.

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