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Beyond Patent Expiry: Rethinking the Future of Mature Medicines in Asia-Pacific

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Dr Varun Sethi, Senior Vice President, JAPAC Region, Clinigen, Explores How Specialist Partnerships, Regulatory Agility and Resilient Supply Chains Are Reshaping Pharmaceutical Commercialisation and Ensuring Long-Term Patient Access



As pharmaceutical innovation accelerates, mature medicines remain essential to healthcare systems, yet their long-term commercial viability and availability face mounting challenges. Across the diverse Japan and Asia-Pacific (JAPAC) region, regulatory complexity, pricing pressures and supply-chain vulnerabilities are prompting pharmaceutical companies to rethink traditional product lifecycle strategies.

In an exclusive interview with BioSpectrum Asia, Dr Varun Sethi, Senior Vice President, JAPAC Region, Clinigen, discusses the evolving role of established medicines, the strategic importance of specialist commercialisation partnerships and how more flexible operating models could redefine sustainable patient access in 2027 and beyond.

As pharmaceutical companies increasingly prioritise innovative therapies and new modalities, what strategic and clinical role do mature medicines continue to play within healthcare systems, particularly across the JAPAC region?

While much of the industry's attention is focused on the next generation of therapies, mature medicines remain fundamental to healthcare systems across the world. Many continue to represent established standards of care in areas such as infectious diseases, cardiovascular health, oncology and chronic disease management, supporting millions of patients every year. Their value lies not only in their proven efficacy and well-characterised safety profiles, but also in the extensive clinical experience that healthcare professionals have accumulated over years, and often decades, of use.

Importantly, not all mature medicines follow the same trajectory after patent expiry. High-volume primary care products may attract multiple generic competitors, creating a broad range of treatment options. However, the picture is often very different for lower-volume or specialist medicines serving smaller patient populations. In these cases, there may be insufficient incentive to encourage widespread generic entry, meaning availability can depend on a more limited number of

suppliers. As a result, these medicines can play a critical role in maintaining continuity of care where alternative treatment options or sources of supply remain limited. This dynamic is particularly relevant across parts of the JAPAC region, where healthcare systems, reimbursement models and access pathways vary significantly. For smaller-volume, specialised medicines, ensuring long-term availability can therefore remain an important consideration even after patent expiry.

Beyond their clinical importance, mature medicines also play a strategic role in supporting the resilience of healthcare systems. While innovation expands future treatment possibilities, healthcare systems depend equally on reliable access to medicines that are already embedded within clinical practice. Ensuring these therapies remain available helps healthcare providers maintain continuity of care, minimise disruption for patients and preserve confidence in established treatment pathways.

Mature medicines can also contribute to supply resilience. As healthcare systems have experienced in recent years, medicine shortages and supply disruptions can arise for a variety of reasons, from manufacturing challenges to global supply chain pressures. Maintaining the regulatory, manufacturing and distribution infrastructure that supports established therapies helps ensure proven treatments remain accessible when they are needed most.

What are the biggest challenges involved in keeping established medicines commercially viable and consistently available once they move beyond patent exclusivity, particularly when managing portfolios across markets with very different regulatory, pricing and distribution environments?

One of the biggest challenges associated with mature medicines is that patient need often remains long after a product has moved beyond its peak growth phase. As medicines move beyond patent exclusivity, they are frequently exposed to increased pricing pressure and competition, particularly in markets where generic entry is well established. While some high-volume products may continue to generate significant demand, maintaining mature medicines over the long term can be challenging given the regulatory, manufacturing and distribution requirements needed to support access across diverse markets.

For larger pharmaceutical companies, this often creates complex portfolio management considerations. As organisations invest in advancing the next generation of therapies, they must balance support for established medicines with the expertise, infrastructure and resources needed to bring promising pipeline assets to patients. At the same time, maintaining the manufacturing, regulatory and market infrastructure required to support mature products across multiple geographies remains a significant undertaking, particularly in regions characterised by diverse healthcare systems and operating environments.

As a result, many companies are increasingly exploring alternative operating models for mature medicines. This may involve partnering with specialist organisations or transferring assets to companies that focus specifically on established brands and possess the infrastructure, local expertise and long-term commitment needed to support them. Such approaches can help ensure that mature medicines continue to reach patients while allowing each organisation to focus on the areas where it can deliver the greatest value.

For biotechs and emerging pharma, building and maintaining local capabilities requires significant investment in regulatory expertise, market access, pharmacovigilance, distribution networks and stakeholder engagement. When managing portfolios across regions with very different requirements, companies need to consider whether to establish these capabilities in-house or work with partners that already possess the necessary infrastructure and local market knowledge.

This consideration is particularly relevant in the JAPAC region, where market conditions can differ significantly from one country to the next. Companies may find themselves navigating multiple regulatory frameworks, reimbursement environments and healthcare systems within a regional strategy. In this context, partnering with organisations that have established regional infrastructure and on-the-ground expertise can provide a more efficient route to market while helping to ensure medicines remain available to patients across diverse healthcare environments.

Regulatory maintenance, demand forecasting, supply planning and distribution can become increasingly complex over a medicine's lifecycle. Where do you see the greatest operational vulnerabilities emerging, and how can companies build more resilient models for mature products?

One of the greatest operational challenges for mature medicines is there is no reduction in complexity as a product ages. In many ways, it increases. Companies need to continue to maintain regulatory registrations, manage supply chains, forecast demand and ensure distribution across often diverse healthcare environments, despite demand patterns becoming less predictable over time. Demand forecasting is a particularly important area of vulnerability. For mature medicines, patient volumes may remain relatively stable, but market dynamics can change quickly. Tender outcomes, the

entry of new competitors, reimbursement decisions or shifts between public and private healthcare channels can all affect demand. Forecasting becomes even more challenging when managing products across multiple countries, each with different prescribing practices and procurement models.

Continuity of supply planning presents another challenge. The presence of registered alternatives does not always guarantee reliable in-country supply, and that supply disruptions can occur even where alternative suppliers exist. In these situations, maintaining manufacturing flexibility, strong inventory management and diversified supply networks becomes important.

The diversity of the JAPAC region adds a further layer of complexity. Markets such as Japan, Australia and New Zealand operate within relatively established reimbursement and healthcare frameworks, while many Southeast Asian countries have a greater mix of public and private provision, creating different demand and distribution patterns. A forecasting or distribution model that works well in one market may therefore not be suitable for another.

Clinigen's partnership with ShanZeBIO will support the commercial infrastructure and distribution of Avelox across 16 international markets. What does this partnership illustrate about the capabilities and infrastructure required to manage established medicines effectively across multiple geographies?

The partnership highlights that managing an established medicine across multiple geographies is far more complex than just maintaining product supply. Even where a medicine is well established clinically, companies need to continue to manage a complex combination of regulatory obligations, supply planning, distribution networks and local market requirements, all of which can vary significantly from country to country.

This complexity is often underestimated. A medicine may have a long history of use and an established clinical profile, but each market maintains its own regulatory framework, commercial channels, procurement processes and healthcare infrastructure. Successfully supporting a product across multiple regions therefore requires not only the ability to manufacture and distribute the medicine, but also the local expertise needed to navigate those differences and respond to changing market conditions.

The partnership also illustrates the value of combining complementary capabilities. Organisations with established regional infrastructure, local manufacturing capabilities and market knowledge can play an important role in supporting mature medicines throughout the later stages of their lifecycle. In some cases, this can help improve operational efficiency, strengthen supply continuity and ensure products remain accessible across diverse healthcare environments. More broadly, it reflects a growing recognition that maintaining access to established medicines requires a highly specialised skill set.

As pharmaceutical companies balance investment in next-generation therapies with responsibility for long-established portfolios, how are specialist commercial infrastructure partnerships changing the traditional product lifecycle model? Where does it make more strategic sense to partner rather than maintain every capability internally?

Historically, pharmaceutical companies often sought to retain end-to-end responsibility for a product throughout its lifecycle. Increasingly, however, the industry is recognising that different stages of a medicine's lifecycle require different capabilities. The expertise needed to discover, develop and launch a new therapy is not necessarily the same as the expertise required to optimise market access, manage complex regional requirements or sustain an established product across multiple countries over the long term.

As a result, specialist commercialisation partnerships are reshaping the traditional product lifecycle model. Rather than viewing external partners as service providers only, companies are increasingly leveraging specialist organisations to provide expertise, local market knowledge and operational capabilities that may be difficult or inefficient to replicate internally. This allows products to benefit from focused attention throughout their lifecycle while enabling innovator companies to concentrate resources on areas where they can create the greatest value.

The strategic decision remains on where those capabilities can be delivered most effectively. For some companies, particularly those managing relatively small portfolios in complex international markets, building infrastructure in every country may not be practical. In these situations, partnerships can provide access to established networks, local expertise and market understanding that would otherwise take years to develop.

The most successful models are often those that combine complementary strengths. Innovation remains critical, but increasingly so does the ability to connect products with the specialised expertise needed at different stages of their lifecycle. Partnerships can help bridge that gap, ensuring that medicines continue to reach patients efficiently while

allowing each organisation to focus on the capabilities it is best positioned to deliver.

Looking towards 2027 and beyond, how do you expect pharmaceutical commercial infrastructure models to evolve, particularly in JAPAC? What role could more flexible partnership, regulatory, supply-chain and distribution models play in extending the sustainable lifecycle and patient availability of established medicines?

Looking towards 2027 and beyond, I think we will see a growing recognition that patent expiry doesn't need to imply the end of a medicine's strategic lifecycle. Historically, the industry often viewed products through a relatively linear lens: development, launch, growth, loss of exclusivity and decline. Increasingly, however, established medicines are entering a new phase in which they are actively managed, repositioned and supported by organisations that specialise in later-stage assets.

This reflects a broader shift in how pharmaceutical companies think about capability and ownership. The traditional assumption was that the company that developed a medicine would also maintain all of the infrastructure required to support it throughout its lifecycle. Today, companies are becoming more selective about where they create value. In many cases, it may make sense to retain ownership of certain capabilities while partnering for others, particularly in regions where building and maintaining local infrastructure would be difficult to justify for a single product or portfolio.

Looking ahead, I expect greater emphasis on matching capabilities to the needs of a medicine at a particular point in its lifecycle. For established medicines, that may mean access to specialist regulatory expertise, local market knowledge, regional supply networks or manufacturing capabilities that can support long-term availability across diverse markets. In a region as varied as JAPAC, where healthcare systems, access pathways and operating environments can differ significantly from one country to the next, this flexibility is likely to become even more important. In this evolving model, patent expiry becomes less of an endpoint and more of a transition point, where the focus shifts from innovation alone to long-term stewardship and sustainable patient access.