Market Access Strategies for APAC Biosimilars

A feature article for PM360 by Phani Kishore Thimmaraju, Senior Consultant at phamax AG

Market access in pharmaceuticals has evolved from being merely price and reimbursement centric to enhancing the patient base by demonstrating the "value" associated with the product. However, in the case of biosimilars, companies need to demonstrate the product performance compared to the reference product, along with safety. Unlike the developed markets where reimbursement plays a crucial role in market access, in the APAC region, price differential plays a critical role in biosimilar acceptance. Also, the regulatory agencies in the APAC, having sensed the growing importance and need for biosimilars, have framed the approval pathways to ensure that the quality of the product is not compromised over the cost. In some of the Asian countries, patients are denied a biologic due to the affordability factor and are limited to treatment though conventional drugs.

Since the status on "interchangeability," which is the key driver for biosimilar uptake, remains unaddressed globally, it is essential to identify the key patient target pool eligible for biosimilars and communicate it to physicians. Owing to incomplete coverage of healthcare expenses in the APAC region and prevailing out-of-pocket conditions, product preference is mostly driven by endorsement of physicians expecting an uncompromised quality—while keeping the price low.

In this context, the market access strategies—when customized to address the region specific situation—would be more fruitful in delivering promising results to biosimilar players.

Customized market access strategies should:

Clearly identify all the relevant patient segments, pinpointing the potential pools for the biosimilars.

While recommending a biosimilar, particularly those of complex biologic mAbs (Monoclonal Antibodies), it should be noted that biologic-naïve patients should be the primary targets. Once the biologic is initiated, it would be difficult to switch those patients to a biosimilar due to underdeveloped regulatory framework on interchangeability. Therefore, a detailed patient journey comprising all the treatment options currently available should be constructed. This helps in arriving at a rough estimate of the number of patients (based on the epidemiology data and applying diagnosis and treatment rate) at each line of therapy and when a biosimilar can be initiated.

Understand the policy development in the APAC region.

It is in the best interest of the biosimilar developing companies to work closely with the regulatory and health agencies of respective countries. This will facilitate an understanding of the bottlenecks and barriers in addressing critical issues on “interchangeability” and “substitution” of biosimilars.

Provide observational studies, patient education/support programs to improve patient access.

In recent years, trends show a larger number of biosimilar companies favoring observational studies to influence stakeholders. The data obtained is not only helpful in conducting various health technology assessment studies but also in gaining trust of physicians and patients by effective “value” communication associated with a biosimilar. Innovative mechanisms such as risk-sharing arrangements to reimburse biosimilars from respective companies will significantly boost the uptake level.

With growing awareness on biosimilars, particularly among physicians, the complete potential could only be realized by showcasing the outcomes from the evidence-based studies highlighting the cost differential factor. Going forward, market access as a function is poised to gain more prominence in formulating strategies that address current needs from a patient perspective, while promoting the product as the best alternative to combat high-cost burdens.

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