Executive Insights

After Faltering Start, Japan's Biosimilars Market Appears on Cusp of Rapid Growth

Japan faces increasingly acute pressure on healthcare finances as its population ages and it struggles with low economic growth. In recent years, drug spending has come under great scrutiny. Significant savings have been achieved by driving penetration of small molecule generics and squeezing pricing for older branded drugs.

In part due to these efforts, Japan has continued to ensure a reasonably favorable pricing and access environment for innovative drugs. As yet, however, biosimilars have received surprisingly little attention from policymakers; few initiatives have been introduced to drive biosimilar uptake and squeeze sales of original biologics.

Nevertheless, with biologics making up approximately 30% of total drug spending and with $4 billion plus of annual biologic sales now at risk, biosimilars are likely a highly impactful avenue for further reducing healthcare spending. What is more, biosimilars (or rather the original biologics they would disrupt) represent a "legitimate" target for policymakers: The vested interests of providers are largely unaffected, biopharmas have little valid cause for complaint (and in any case, many are hedged), greater funds are available to support innovation, the overall sustainability of the system is reinforced, and patient care is not compromised.

Market seems to be finally living up to its billing

Yet despite the apparent alignment with macro-trends and the interests of market constituents, the prevailing view in the market was — until recently — that biosimilars would struggle to gain traction. With few incentives for substitution, limitations on switching and a strong prescriber bias for safety and quality, it seemed that biosimilars would face as tough or even tougher a market than did small molecule generics earlier in the century, before the Japanese government took decisive measures to drive generic adoption. Market commentators pointed to specific examples where biosimilars failed to penetrate the market (somatropin, infliximab), to make their point.

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However, the recent launch experience for several biosimilars points to a very different market trajectory. There have been a number of notable successes, even absent the types of measures that were needed to catalyze the small molecule market, and growing development activity. Sandoz for example successfully captured 30% of the rituximab market within a year or so of its product's launch. Ayumi Pharmaceutical had to limit supply of its Enbrel biosimilar on account of its popularity.

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What has changed? For sure, the government has been making noise in support of biosimilars, but as yet, few significant efforts to modify market barriers and incentives have followed (not to say that these should not be anticipated going forward). The fundamental driver it seems is raw economics; the cost calculus of biosimilars makes solid sense for several market actors. For the most part, patients benefit from smaller copays. Japan's economy isn't what it was, and older patients in particular face stretched budgets and have limited disposable income. Physicians are far more sympathetic to the financial situation of their patients than they once were, and more likely to accommodate these considerations in their prescription decisions than was the case five or 10 years back. Such sensitivity to patients' economic realities seems often to outweigh the broader concerns around clinical equivalence or quality that market observers had expected to derail the market.

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For hospitals as well, where certain biologics are paid for out of case-based payments (e.g., filgrastim), there is a strong incentive to bank the extra margin that these biosimilars permit versus original biologics. Against a backdrop of increasing financial pressure on providers, it is no surprise that hospitals have eagerly adopted these biosimilars. Other factors — manufacturers partnering with highly reputable commercial partners (Sandoz partnered with KHK to market its rituximab biosimilar), an absence of concerted legal challenges to biosimilar entrants — have also supported development of the market.

The biosimilars market still faces challenges: lack of clarity around the amount of clinical development required; still-weak incentives for substitution; and the vagaries of the reimbursement system and certain subsidy programs resulting in copays being lower for the original biologics versus biosimilars for some therapies in certain indications. The most concerning of these challenges is the advent of "biosames," follow-on biologics that are identical to the original, require no additional development, use the same manufacturing lines as the original and can essentially launch nearly immediately upon loss of exclusivity for the original biologic. There are concerns that biosames will stifle market development, given their quick and cheap route to market in an industry where order of entry is key, although it is too early to say how scarring this development will be. Yet as already noted, driving biosimilar market development should be a policy priority for the reasons described above. Thus, it is reasonable to expect the government will make further efforts to address such challenges, perhaps including measures to level the playing field between biosimilars and biosames.

Careful forward planning needed to maximize success as the market develops further

Companies developing biosimilars need to soundly assess the business case for a given molecule, and properly understand the economic drivers and barriers to their molecule when considering pursuing the Japan opportunity. Go-to-market planning is also paramount: Should they partner and, if so, with whom? Do shifting purchasing dynamics (e.g., regional and hospital group formularies, increasing prominence of economic purchasers) offer novel go-to-market opportunities? Such planning needs to be done with an eye on what the future market landscape may look like and not be anchored solely in the present.

For originators, the dynamics of their markets will likely shift dramatically. What can these players do to increase their "stickiness" and extend their value propositions in increasingly crowded markets (e.g., additional indications, new formulations, pricing strategies)? For those considering launching biosames, is there truly a compelling business case for doing so, and how should they position the biosame versus the original upon eventual launch? Even if prevailing market dynamics create structural barriers to biosimilars' entry and adoption, originators should expect that the environment will likely change in the future.

For the biopharma industry in Japan more generally, the unleashing of the biosimilar market should be cause for celebration: System sustainability is critical to all, savings to the system that can be reinvested in true innovation are to be cheered, and the industry dearly needs examples of its contribution to the health and wealth of society.

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