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How to approach an increasingly challenging and subjective Japanese pricing environment

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Japan remains on balance an attractive pharmaceutical market, with favorable volume dynamics, generally attractive pricing and broad and unfettered market access, writes Patrick Branch from LEK Consulting, in an Expert View piece.

However, pricing has become more challenging over recent years – both in terms of how rules are designed and, less obviously to the outside, how they are prosecuted by the Ministry of Health, Labor and Welfare (MHLW) – and many companies have been caught out by these shifts.

Companies need to approach Japan pricing with their eyes wide open in order to set expectations appropriately and devise effective strategies to optimize price at the time of launch and thereafter.

The years of plenty and eventual backlash

Ten to 15 years ago, Japan was a market where clinical development was costly, it took a long time to navigate the regulatory process, but once you got to market you were rewarded with an attractive price, albeit one that was eventually subject to biannual price cuts that would slowly grind away at the revenues and profitability. Japan was viewed as a decent market, but one which had its trade-offs.

During the early 2010s, that equation shifted considerably: acceptance of global clinical trials for regulatory filings, substantial improvements in regulatory-body throughput, new mechanisms to limit price-cuts for innovators, and an access environment that ensured immediate nationwide availability and capped copays meant that many manufacturers could have their cake and eat it.

Suddenly Japan was the most innovation-friendly market in the world.

This precipitated a period of market growth in Japan, punctuated by ‘first-in-world’ launches, providing welcome respite from the increasingly bleak pricing and access landscape in other major markets, as manufacturers realized they could launch early at high prices with little foreseeable price pressure over the lifetime of the products.

The eventual backlash arrived mid-way through the 2010s, triggered with the pyrrhic success of Opdivo (nivolumab), which achieved a launch price three times what it received in the USA, and Sovaldi (sofosbuvir) ramping to a near $2 billion drug in under two years, and against a backdrop of increasing pressure on healthcare finances and growing influence of the Ministry of Finance and Cabinet Office over healthcare spending. The Japanese government was becoming increasingly aggrieved at the apparent revenue and profitability excesses of pharma and also saw opportunities to cut pharma spending down to-size.

Measures in place to manage down pricing

After a short period of debate – in which the industry played little role – a battery of measures were introduced over the course of two-or-so years, designed to curb what were perceived to be the most egregious practices of industry. These measures included the following:

- Rules to drastically cut price in the event of substantial overshoot of the revenues forecasted at the time of initial pricing, typically in the event of indication expansion;

- Limitations on which drugs could receive pricing protection for the exclusivity period of the drug;

- More discriminating application of the foreign pricing adjustment rule to avoid big upward adjustments and the resulting pricing disparities within the same classes of drugs;

- A one-off application of foreign pricing adjustments for select drugs deemed to have achieved Japan pricing far in excess of eventual pricing in other major markets;

- Increased frequency of price revisions (annual, and for some drugs quarterly, assessments);

- Rapid price cuts post-LOE, designed to drive originator pricing down to that of generics

- Usage guidelines to limit prescribing of potential budget-busting drugs;

- HTAs for drugs exceeding certain revenue thresholds or being viewed as high-priced.

The spirit of the rule changes was understandable: Japan, like all other major markets, is struggling with healthcare costs; aging populations present the challenge of low economic growth and further growth in demand for healthcare; innovation offers therapies that, while addressing unmet medical need and potentially longer term economic value, are costly in the context of annual healthcare budgets.

However, the tools that were introduced were very blunt and not necessarily supportive of Japan’s objectives to ensure access to world class healthcare or its longer-term economic interests. For the most part the measures have been designed reactively, emerging from responses to specific instances where a drug’s pricing was deemed to take advantage of the design of the pricing system.

What’s more, in many instances they serve to pour water on innovation – and not innovation for its own sake, but innovation that saves both lives and yen.

Meanwhile, big pockets of spend went relatively untouched – old branded drugs that are generally OTC in other markets continue to be reimbursed, off-patent biologics enjoy large market share (although are now the subject of scrutiny).

Few compelling mechanisms exist to reward economic innovation or permit pricing model innovation.

There is a further, less well-documented but increasingly pervasive development; one not documented in the rules themselves but evident in the behaviour of the MHLW during pricing negotiations and a close read of pricing decisions. The MHLW clearly approaches pricing decisions with thresholds in mind as to what it is willing to pay. These thresholds are typically based upon anchor points such as the price of local comparators (even if not explicitly referenced in the formal interpretation of the pricing rules), pricing in overseas markets deemed most analogous to Japan (note, not necessarily the average of the full FRP ‘bucket’), and cost assumptions used to price drugs in the past.

Willingness to pay does not necessarily reflect what the system can pay, rather this reflects a sense of what is reasonable or ‘fair’ for Japan to pay given the presence of tangible anchors and infused by the embarrassment caused in the 2010s where stakeholders expressed dismay at some of

the MHLWs pricing decisions. The MHLW will permit a delta on top of these anchor-points, but only to a point, and once fixated on a clear anchor it would seem a delta over two-times the anchor is not so commonplace.

On the face of it, this appears a reasonable and potentially positive development, as it would suggest the opportunity to posit compelling anchors. In practice this plays out to push prices lower versus what would otherwise be the case based upon a faithful interpretation of the rules.

How this manifests is as follows:

- A strong bias towards comparator-based pricing, even when local comparators do not technical qualify;

- Creative definitions of comparators;

- Refusal to apply the FRP rule, or inconsistent or seemingly biased application of the rule (eg picking specific markets to benchmark, arguing overseas indications are different to that being pursued in Japan);

- Ostensibly applying the cost-plus method, but the outcome strongly indicating that an old therapy had been implicitly benchmarked to engineer far short of what the company had likely required to justify the business case.

How companies should approach pricing in Japan

So how should companies be thinking about pricing and access in Japan, and the Japan market more generally, given the above?

Overall, Japan remains fundamentally an attractive market with generally favorable pricing and access and other favorable attributes not covered in this article. Price points tend towards the average of the EU3, all approved drugs get priced (assuming agreement can be reached), all priced drugs get access, and access is typically immediate, nationwide and largely unencumbered.

Gross-to-nets are relatively modest. Companies should thus not overlook Japan, but they should understand the pricing system and anticipate and plan for potential challenges both in advance of and subsequent to launch.

In preparation of the critical initial pricing steps, companies are thus well advised to put themselves in the shoes of the MHLW and think through a few things as they evaluate pricing and develop their strategy. Questions that should be considered include the following:

- What are the anchor points that the MHLW may refer to in the first instance as part of its ‘range finding’? If no apparent anchors, fine, but companies should not be naïve here and not rationalize away anchor that appear intuitively comparable, if intellectually dubious;

- What are the scenarios as to how the pricing rule could be interpreted? Where would these lead us in terms of pricing ranges? Given what we anticipate in terms of MHLW anchors and objectives, which pricing approaches do we expect to be more / less likely?

- What further negotiation can we expect from the MHLW? What pricing levers are they likely to target given legitimacy of targeting these and impact on the resulting price?

- What can we do to engage effectively with the MHLW through this process? What anchors can we suggest ourselves? What arguments can we make to undermine the logic, legitimacy of unfavorable MHLW positions? What data – clinical, scientific, even economic – can we use to serve this end?

- How can we optimize the timing of data publications and regulatory and pricing applications in other markets to support Japanese pricing (and vice versa).

Post-launch, companies should continue to be vigilant and carefully track how regulatory activities as well as commercial success may trigger pricing changes, as well as exploit opportunities to drive improved pricing. Questions that companies should be asking themselves include the following:

- Will the product be eligible for HTAs? What do we need to be doing now – data collection, literature review, analyses design – to get ourselves ready for this?

- What might trigger further, unexpected pricing changes? How might dosing changes for example precipitate repricing? How can we anticipate and ward this off through our regulatory activities and direct communications with the MHLW?

- What can we do to bolster pricing? How can we leverage real world evidence to support pricing premiums? How can we extend our product – pediatric approval, orphan designation – to improve pricing?

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