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Asia's Outsourced Pharmaceutical Future

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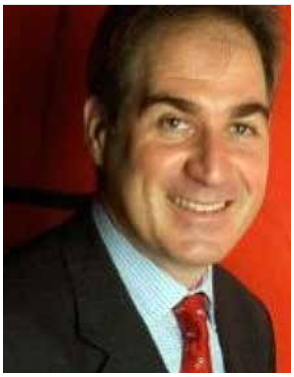
In the summer of 2019, the government of Japan released – then retracted – an economic forecast that stunned the nation. It predicted pension income would fall drastically short for married couples in their 60s expecting to live another 30 years. As health care and other age-related costs increased over time, the couple would need to find an additional 20 million yen ($184,000) in assets.



SEBASTIAN BATHER

Around the same time, Chinese families were hearing more and more from their government about shortages of cancer drugs, hospital beds and other medical goods and services. Despite new government policies to increase availability of cutting-edge treatments, supply wasn't matching demand from China's fast-growing middle class.

These intertwined trends – economic growth, aging populations, mounting demand for high-quality care and policy reforms to meet those needs – are not limited to Japan or China. They're unfolding to varying degrees all across Asia-Pacific (APAC). One telling indicator: in 2018 nearly half the world's new cancer cases – and more than half of all cancer-related deaths – occurred in Asia, according to the World Health Organization's International Agency for Research on Cancer. Yet, the region accounts for nowhere close to 50% of the world's supply of provisions or services for such patients – whether it's available hospital beds, numbers of surgeons and nurses to attend to patients, or supplies of medicines to make them well.

POWER IN PARTNERSHIPS

Demand for better health care, along with its tangled demographic drivers and policy consequences, has opened up dramatic new opportunities for multinational pharma companies seeking to offset slower growth in Europe and the US. And yet, many multinationals are struggling to grow their businesses in Japan, China and other Asian markets at a time when each step forward comes with new regulatory and operational hurdles. Already, it is all but impossible for pharma to achieve its goals for growth in the region with a go-it-alone strategy. Success will hinge on how effectively pharma shares responsibilities with purpose-built networks of collaborators and outsourcing partners.

The good news is, multinational pharma firms with robust partnerships across Asia are already absorbing valuable lessons as government policies evolve in response to demographic pressures – most importantly, aging populations with rising demand for high-priced pharmaceuticals. In addition, business innovations these companies adopt in Asia will likely serve them well in Western markets as more nations come under similar pressures.

A quick review of recent changes in the pharma landscapes of Japan and China will show why sector-leading multinationals are deepening their reliance on outsourcing and how such partnerships can deliver the desired efficiencies.

JAPAN'S PRODUCTIVITY PUZZLE

The government of Japan has been charting economic policies with an eye to its aging population for many decades. But only recently, in 2016, did intersecting concerns about elder care costs and high drug prices translate into action. That year, amid public alarm about expensive cancer immunotherapies, Japan's policymakers introduced a drug repricing rule that led to hefty price cuts on treatments for cancer, hepatitis C, blood thinners and other products. In a series of price reviews, the government halved the reimbursement price for Ono/Bristol-Myers Squibb's Opdivo and took action on other high-priced treatments.

Japan's Ministry of Health, Labor and Welfare (MHLW) is now walking a fine line between supporting and paying for leading-edge medicines. As part of this balancing act, the ministry is pulling the rug out from under products still having market exclusivity – if you're second or third to market in an important new class of cancer treatment, your chances of getting premium pricing are slim.

At the same time, Japan wants to be in the first wave when companies launch important new treatments, preserving its reputation as a haven for pharmaceutical innovation and a leader in care delivery. But, because patients respond differently to immunotherapies and other advanced treatments, tough pricing policies that constrain physicians' choices often

do not serve the best interest of health care consumers.

How can pharma's strategic planners best respond when products still under market exclusivity suddenly undergo 30% to 50% price cuts? And, how can this response simultaneously take stock of social and cultural shifts, such as changing physician preferences on how they interact with medical reps? Solving this productivity puzzle often exceeds the reach of a sparsely staffed Tokyo-based subsidiary of a multinational pharma company. It's a challenge best addressed in collaboration with contract commercial organizations (CCOs) that specialize in agile adaptation to landscape transformation.

The pharma field force in Japan relies on relationships and face-to-face interactions with physicians who traditionally have had a strong influence over which brand of drug is prescribed. Because of accelerated price cuts in mature portfolios, especially in primary channels, the economics of maintaining face-to-face (F2F) relationships haven't just turned ugly – they're totally unsustainable. Communication must shift to more cost-effective digital channels. But, companies are finding it hard to drive change. CCOs, with deep expertise in multichannel marketing and the ability to combine digital and F2F interactions into a cost-effective hybrid model, can be part of the answer.

As in many advanced markets, reliance on medical science liaisons is growing quickly in Japan, and wider use of non-promotional key opinion leaders (KOLs) will follow. In 2017–18, the number of MSLs increased by 23% in Japan. What companies need now is a cost-effective way to build MSL capacity by preparing science-background PhDs and PharmDs with comprehensive programs and continuing training. Leveraging their global experience and competency models, multinational outsourcing organizations excel at combining recruitment, training and development of MSL teams.

RETHINKING CHINA'S INTENT

Commentators on China's market reforms tend to highlight improvements in the clinical research environment stemming from a series of recent moves by the National Medical Product Administration (NMPA – formerly the China Drug Administration). Certainly, measures such as the 60-day automatic trial approval process and tax incentives that pressure Chinese biotechs to seek approval in global markets from day 1 when developing a new molecule have radically altered the R&D environment. But, when developing strategies around these regulatory changes, multinational organizations must also not lose sight of China's intent. Fundamentally, the NMPA seeks health care parity with advanced Western countries, which means expanding local access to the most effective medicines regardless of where they were developed. This is why China has dismantled barriers to use of data from trials conducted outside its borders. By focusing on the intent rather than research policy minutiae, multinationals will see that the reforms have even bigger implications for how pharma prepares for a commercial launch in China than how many trials it can get off the ground, or how quickly.

In 2017, China launched 21 new compounds, more than the previous three years combined. As of last year, there were another 48 products China wanted multinational pharma to bring to market and is offering conditional approval that clears the way for accelerated launch. NMPA is saying, in effect: no need to run the trial – registration will suffice. That leaves multinationals with a heavy lift, to be sure – but it's not in R&D. They must put together commercial teams that can manage every stage in the product launch.

Regional headquarters of even the largest pharma simply aren't built to manage simultaneous launches of multiple key products. But, a global CCO partner knows the whole playbook – from advice on the registry process and market segment analysis to evidence generation, KOL mapping and engagement, assembling medical affairs teams, real-world evidence and postmarketing surveillance.

Once a drug company wins marketing approval, it faces a variety of pricing hurdles. In a winner-take-all formula that trades volume for price, the central government is putting pressure on brand owners to submit the lowest-possible bid for business that may include all hospital systems in a major urban center such as Beijing, Shanghai or Guangzhou. The reward is massive volume, albeit at a very low price. But, often it's a winner-take-all contest in which few foreign multinationals are victorious. New volume purchasing guidance means, in the rosiest scenario, reduced drug pricing, and in the worse case, losing the tender altogether.

FINDING COMMON GROUND

While demographics driving regulatory reform and innovation in commercial models may differ across Asia, success in these markets always will hinge on correct understanding of government intent and the changing rules of the road. In Japan, drug pricing reform is the response to a looming crisis where an aging population will cost the government more, with consumers shouldering greater out-of-pocket costs as well. Pharma must adopt plans that support the country's economic, societal and reputational ambitions. China is not so different. Beijing's goals have less to do with matching the West's clinical trial prowess than raising health care standards for the greatest number of people by increasing access to effective medicines. With reduced investment dollars across the portfolio, foreign multinationals must look for more cost-effective ways to launch and promote products. It's the only way to ride the tailwinds of improved access under regulatory reforms favoring R&D.

Navigating the push-and-pull of complex government-led agendas is not something any company should attempt on its own. By grooming broad, collaborative, outsourcing-optimized business networks, pharma companies will find they have all the resources they need.