CPHI JAPAN IS PROUD TO PRESENT
IQVIA MARKET PROGNOSIS 2023-2027

Japan

Published March 2023

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Published: March 2023

FOREWORD

IQVIA and CPhI are pleased to bring you our special Market Prognosis report sharing our view of the future of the Japanese pharma market. Both CPhI and IQVIA consider that such information is key for the growth and development of the pharma industry and believe that this report will provide valuable insight as you look to develop your business in Japan.

The report provides an evidence-based outlook for Japan based on the knowledge of our country experts who carry out extensive research into key business and healthcare events and apply this to a gold standard historical view of the market.

We are excited to share this valuable country information with you and look forward to welcoming you to CPhI Japan.

CPhI and IQVIA team

MARKET OVERVIEW AND FORECASTS

Market Synopsis

- The Japanese pharmaceutical market is forecast to decline at a CAGR of 0.1% (±1.5%) between 2022 and 2027, reaching ¥12,442 billion (at public prices) by 2027.

Business Environment

- Economic growth is expected to remain tepid, with real GDP growing at 1.0% in 2023. The recovery will be weak as the inflationary effects of the war will linger and continue to weigh on private consumption. Expansion will continue at a modest pace between 2024-2027, supported by the stable employment and the push from Mr Kishida's 'new form of capitalism' agenda, which advocates faster wage growth. Consumer prices will increase by an average of 1.9% in 2023, moderating from 2.5% in 2022. Firm inflation in the first half of 2023 will constrain consumption growth and business investment, but will ease sharply in second half of the year. Inflation will trend downwards thereafter at an annual average of 0.8% during 2024-2027. The yen is forecast to strengthen against the US dollar, reaching an average of ¥123.60:US$1 in 2023. The yen's nominal exchange rate against the US dollar will strengthen further in 2024-2027, to reach an average of ¥108.80:US$1 in 2027.
- The prime minister, Kishida Fumio, and his government will prioritize supporting economic growth, which will necessitate continued fiscal stimulus in 2023. Beyond the immediate task of reviving the economy, the government has marked digitalization, investment in research and development and clean energy as engines to propel Japan's long-term growth.

Healthcare Provision

- Japan's rapidly ageing population will place increasing strain on the healthcare system and sustaining universal healthcare provision will require some level of reform to the National Health Insurance (NHI) system. The need for cost-containment could, however, force rationalization of benefit coverage in the longer term. This will be challenging due to cultural expectations of broad access to subsidized healthcare and medicines.
- Digitalization of the healthcare system is progressing, albeit slowly, and will eventually lead to more efficient provision. The ability of the healthcare system to fully harness the benefits are being hampered in the short-term by some basic shortfalls; for example, electronic medical records are being used by most hospitals but lack of a national platform for information exchange, hinders provision of more holistic care.
- To enable broader use of clinical data in the healthcare system, the government has initiated digitization measures to link all patient records to an online individual ID system. Existing health insurance cards are to be replaced by 'My Number' identity cards by autumn 2024, which will increase the autonomy of patients in managing their healthcare as well as support drug discovery and clinical studies in the future.

- Pharmaceutical expenditure will be a key topic of discussion within the Ministry of Health, Labor, and Welfare (MHLW) in the early part of the prognosis period. The Ministry of Finance (MoF) is of the opinion that concerted measures to address the unpredictability of the drugs bill are needed, while the MHLW is keen to ensure a system that supports both the domestic industry and foreign investment to ensure patient access to medicines is not compromised.
- Strengthening primary care and promoting disease prevention are high on the government's agenda. Gradual emergence of an integrated community care system (ICCS), supported by recent improvements in adoption of telemedicine, will help to shift the focus of provision away from curative, hospital-based care, although a shortage of doctors remains problematic.

Prescribing and Dispensing

- In January 2023, the MHLW rolled out a national electronic prescribing system, following completion of a pilot project initiated in September 2022. The system is expected to be instrumental in reducing duplication errors, as well as identifying contraindicated medicines, and reducing instances of polypharmacy.
- As part of the government's healthcare digitalization drive, physical health insurance cards will be replaced by personal identification numbers known as 'My Number'. With effect from April 2023, the government will make checking of individual's My number card mandatory across all prescription pharmacies, clinics or hospitals in Japan. The checks will be made using a dedicated online system called the Online Verification System '*Shikaku Kakunin Toh*', which will also form a foundation for the national clinical records platform.
- Although somewhat delayed, generic utilization rates are now approaching the government's target of 80% in most prefectures. Generic prescribing and dispensing premiums, available to medical institutions and pharmacies that achieve generic targets, have been instrumental in boosting consumption but are now attracting the attention of the MoF, which sees them as redundant. Rather than scrapping them, the MHLW has made add-on premiums available until December 2023 as part of measures to address supply shortages in the market. Critics claim the premiums now do little more than increase co-payments for patients.
- Increasing the number of hospitals that have a standardized formulary is seen as a necessary development to improve patient outcomes by standardizing evidence-based treatment and reducing pharmaceutical expenditure, not least due to the ability to leverage greater purchasing power. The over-riding aim is cost-containment and therefore generics will be favored in preference to off-patent brands (referred to locally as long-listed products, LLPs).

Pricing and Reimbursement

- Japan's pricing and reimbursement system has presented some major concerns for the innovative industry as successive amendments to price maintenance premiums (PMPs) have exposed products to deeper price cuts during the NHI biennial price cuts, resulting in progressive price erosion of patented brands. Further amendments have seen revisions made that levy substantial price cuts on products that achieve unexpectedly high-volume sales, or which are approved for new indications that significantly expand the eligible patient population.

- The pricing environment is considered a major contributor to Japan's increasing risk of drug margin loss, or drug launch lag, where innovative new medicines are concerned. The MHLW has thus mandated expert committees within government (including a newly established distribution and drug pricing panel) to consider how the current system can be reframed to better reward innovation, whilst also protecting the public healthcare fund from excessive pressures. Revisions could be implemented in FY2024. For the innovative industry, maintaining prices for the duration of a product's lifespan is a key priority.
- Intense competition in the highly fragmented generics sector has rendered prices of some generics so low that they are now virtually unprofitable, calling into question the stability of a sector that is already struggling with supply issues. Consolidation of the sector is a necessary development to establish a market of high quality and high production capacity, but the transition could risk further supply shortages. The MHLW is carefully considering how pricing policy can be reformed to support this process.
- The second off-year NHI price revision will be implemented in April 2023. The price adjustment rate has been set at 2%, exposing almost 70% of the market (18,197 products) to price revisions, far higher coverage than the industry had hoped for off-year revisions. In acknowledgement of the pressure on manufacturers, the MHLW has implemented a one-off concession for 150 patented medicines that would otherwise have undergone a price cut had price maintenance premium (PMP) rules been applied. Similarly, some 1,100 unprofitable generic medicines will be granted a price rise.
- Margins within the pharmaceutical supply chain have been steadily eroding, causing issues for all stakeholders, a situation that will accelerate with the imposition of off-year NHI price revisions. With the MHLW focused on revising the pricing framework, the discussion must inevitably address the substantial challenge of the *yakkasa* – the difference between NHI reimbursement prices and actual transaction prices – upon which pharmacies and medical institutions heavily rely for profits.

Regulatory Environment

- Ensuring that Japan is one of the first countries to approve innovative new medicines remains a high priority for the Pharmaceuticals and Medical Devices Agency (PMDA). The *Sakigake* system, which provides an accelerated development and approval pathway, is central to this objective but the number of qualifying products is in decline.
- Domestic manufacturer Shionogi is the first company to benefit from the emergency approval system established in May 2022 to allow swifter approval of medicines and vaccines urgently needed in emergency situations (such as a pandemic) for which there are no alternative therapies. Xocova is currently indicated for the treatment of mild to moderate COVID-19 regardless of patient risk factors. Given this indication, critics have called into question whether Xocova is an appropriate candidate for this pathway. The PMDA may need to consider applying the qualifying criteria more closely in future.
- The PMDA is striving to increase its capacity to evaluate real-world data (RWD) in recognition of the value of such data for innovative products for which attaining large-scale clinical trial data may be challenging (such as for products indicated for rare diseases). As such, ensuring the integrity

and credibility of sources of information, such as patient registries, as well as scaling up expertise within the agency itself to evaluate it, are currently an area of keen focus.

- A series of good manufacturing practice (GMP) violations affecting some high-profile domestic manufacturers has shaken the industry over the past several years. The PMDA is working to repair the damage by ensuring that all prefectures have the expertise and capacity to conduct quality inspections. The agency is also proactively supplying information to manufacturers to support them in revising their standard operating procedures in a bid to reduce the number of future violations. Public confidence has been undermined and will take some time to restore, however.

Pharmaceutical Business Environment

- Leading domestic manufacturers posted strong growth in 2022, underpinned by revenue from overseas markets, which was also boosted by a weaker yen. Prospects in the early part of the prognosis period may dampen slightly, however. For the foreign industry, the aggressive pricing and reimbursement framework remains a major challenge and will deter some from investing in the market as a global priority, unless the government intervenes.
- The demands of the COVID-19 pandemic have refocused attention on the importance of the pharmaceutical sector however, and, as such, the government appears more committed to taking measures to support innovation, improving prospects for multinationals in the medium term.
- Measures to develop domestic R&D activities will increase significantly in a bid to boost Japan's capacity to develop and commercialize innovative new drugs and vaccines. Cross-sector collaboration will be facilitated and measures to attract venture capitalists, to support the local industry, will be taken. Efforts to reduce reliance on foreign produced active pharmaceutical ingredients (API) will also provide an important boost to the domestic industry.
- The distribution sector, still fragile from the impact of the pandemic, has also suffered a series of bid-rigging scandals which has resulted in fines being imposed on some companies, a factor which has not deterred the practice. Profit margins are low, and declining, and while larger players are rapidly diversifying their interests to sustain profits, smaller players may struggle to remain viable.
- The OTC market continues to suffer from relatively tight regulation, a sluggish switch-climate (despite efforts by the MHLW to stimulate switching) and, most significantly, the fact that OTC-like medicines are available on the NHI reimbursement list. The market has been contracting in both volume and value since the start of the COVID-19 pandemic and some potential towards recovery to pre-COVID levels is possible; however, the Chinese shopper trend, which was an important driver of the market pre-2020 is unlikely to fully recover.

Total Market Forecasts 2023-2027

The total pharmaceutical market is expected to decline at a CAGR of 0.1% (±1.5%) during the period 2022-2027.

Key Issues Affecting Market Growth

Key Drivers	Key Constraints
Measures to facilitate access to innovation. New product launches will remain a key contributor to growth as the government takes steps to encourage and reward innovation by broadening the eligibility criteria for price premiums, utilization of the *Sakigake* and the emergency approval system, as well as adoption of real-world data to expedite the review of high priority medicines.	**Annual NHI price reviews.** Drug prices will be subject to annual cuts following the introduction of 'off-year' price reviews since 2021. These will target drugs with high *yakkasa.* Though the impact of off-year reviews is expected to be of lesser magnitude than biennial revisions, it will limit the extent to which sales recover in the interim period. The next revision is scheduled from April 2023.
COVID-19 pandemic impact (recovery). Hospital sector volume, which was significantly impacted by the COVID-19 pandemic due to postponement of non-urgent treatments, continued to be suppressed in 2022. Demand recovery will continue through the first half of 2023 as further patient backlog cases are addressed.	**Increased uptake of generics and biosimilars.** Price erosion following the loss of exclusivities of key patented products and entry of generics and biosimilars, the implementation of revised utilization targets for generics and biosimilars, and measures to increase prescribing of biosimilars, will constrain pharmaceutical market growth over the forecast period.
Rapidly ageing population. A rapidly ageing population will place increasing pressure on the healthcare system, driving up both demand and treatment costs. The rising 65+ years cohort is expected to expand to ~30% of the total population by the end of the prognosis period and social security spending is expected to skyrocket as post-war baby boomers start turning 75 years old.	**Restrictive pricing framework.** Amendments to the re-pricing rules, restrictive price premium criteria and cost-effectiveness assessments (CEAs) will erode innovative drug prospects. Reform of pricing rules for 'long-listed products' will result in earlier, more substantial price cuts. Generic prices will also remain under pressure over the forecast period.

Source: IQVIA