

 **CPhI**korea
IS PROUD TO PRESENT

IQVIA™ MARKET PROGNOSIS 2018-2022

South Korea

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FOREWORD

IQVIA and CPhI are pleased to bring you our special Market Prognosis report sharing our view of the future of the South Korean 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 South Korea.

The report provides an evidence-based outlook for South Korea 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 Korea in Seoul.

CPhI and IQVIA team

MARKET OVERVIEW AND FORECASTS

Market Synopsis

- The South Korean pharmaceutical market is forecast to grow at a CAGR of 4.7% ($\pm 1.5\%$) between 2017 and 2022, reaching Won19,999 billion by 2022.

Business Environment

- Real GDP growth is expected to fall from 3.2% in 2017 to average 2.7% in the period 2018-2022. Except for an anticipated slowdown in the US economy in 2020, external demand will remain supportive for South Korea's export-led economy throughout the forecast period. Inflation is expected to accelerate to an annual average of 1.8% in the period 2018-2022, owing to a moderate rise in global oil prices. Following a strong performance in 2017, the won is forecast to depreciate against the US dollar during 2018-2020, before strengthening steadily on the back of improved global trade growth towards the end of the forecast period – to an average of Won1,144:US\$1 in 2022.
- Elected in May 2017, the South Korean president Moon Jae-in of the Minjoo Party is expected to serve the full five-year term. Although not holding an overall majority in the National Assembly (parliament), the administration has made steady progress on pushing through the assembly its ambitious social and economic policy agenda – focusing on welfare benefits expansion and the creation of a higher value-added economy. The next parliamentary election is scheduled for April 2020. Despite Mr Moon's re-engagement efforts with North Korea, a deep rapprochement appears unlikely and inter-Korean relations will remain a security risk through to 2022.

Healthcare Provision

- Announced in August 2017, the 'Moon Jae-in Care' – dubbed 'Mooncare' – will be the most important factor affecting the healthcare environment over the next five years. The drastic expansion of reimbursement coverage stipulated under the reforms will see National Health Insurance (NHI) coverage grow from the current 63% of total medical expenditure to 70% by 2022.
- The plan envisages the expansion of reimbursement coverage to all serious diseases – beyond the four major therapy areas (cancer, cardiovascular, cerebrovascular, rare diseases) that have been targeted for increased reimbursement coverage since 2013. Some 480 drugs, which are not currently reimbursed, will be gradually brought into reimbursement between 2019 and 2022, with differential co-payment rates of 30%, 50% or 80%.
- The government expects the implementation cost of Mooncare will amount to Won30.6 trillion over the next five years, although critics believe the cost will be significantly higher. Coupled with demographic and epidemiological trends, the drastic reimbursement expansion under Mooncare could push the NHI system into annual deficits as early as 2018, forcing policymakers to pursue new cost-containment policies.

- A major extension of the diagnosis-related group (DRG) system and the introduction of global budgets or reference pricing are among the cost-containment policies that the government may consider. These proposals will meet with strong opposition from healthcare institutions and medical professionals, however, and pharmaceutical spending is expected to remain a favored cost-containment target.
- The government is likely to try to generate pharmaceutical savings by targeting the off-patent original/generics sector, where existing prices remain relatively high by international standards. Potential options also include the introduction of global budgets for pharmaceuticals and the imposition of price reduction, while a longer-term prospect is the introduction of mechanisms to encourage generic price competition.

Prescribing and Dispensing

- The Health Insurance Review and Assessment Service (HIRA) will continue to dictate doctor prescribing decisions through its reimbursement guidelines, drug utilization review, quality assessment service and other programs. Prescribing behaviors will be subject to growing scrutiny, with HIRA offering financial incentives to or imposing penalties on providers in order to drive high-quality and cost-effective prescribing.
- Policymakers are promoting a wider adoption of tender-based procurement for multi-source drugs in hospitals. In addition to encouraging price competition, the tendering process will lessen the influence of doctors, and hence the role of illegal rebating, on purchasing decisions.
- Levels of generic prescribing and substitution will remain low, unless the confidence level in generics can be improved among doctors and patients. In order to boost generic usage rates, more substantial incentives for doctors and pharmacists to use lower-priced products will also be required.

Pricing and Reimbursement

- Pressure on reimbursement prices will remain intense, as the authorities try to keep NHI costs under control. Price cuts in the second half of the prognosis period are a possibility if Mooncare puts too great a strain on the NHI budget.
- Mechanisms have been introduced to give higher prices to new drugs, in response to domestic companies developing biosimilars and multinationals reluctant to introduce new drugs if a low Korean price affects prices in other markets. Companies will lobby the authorities to do more, and the multinational industry will fight for the benefits given to local companies to be extended to them as well. The issues of new drug prices and discrimination will feature in the free trade agreement renegotiations between the US and South Korea.
- There are hopes that risk-sharing agreements (RSA), which provide benefits to patients, the NHI and companies, could be expanded under Mooncare as a way of widening insurance coverage. However, the hostility of some National Assembly members and civic groups to the system makes this development uncertain.

- The price-volume agreements (PVA) system may be amended to include blockbuster drugs already on the market, which will have a severe impact on the industry. Domestic companies can now pay refunds rather than suffer price cuts, in order to protect their prices in export markets.
- The exclusion of leading tertiary and general hospitals from the biennial actual transaction pricing (ATP) price survey will encourage fierce price competition for tenders issued by these institutions, since companies will no longer have to worry about a price cut as a consequence of offering a low tender price.

Regulatory Environment

- The Ministry of Food and Drug Safety (MFDS) will continue to upgrade regulatory standards and improve the efficiency of internal processes. As well as ensuring the safety and quality of drugs on the market, this will help to boost the global competitiveness of domestic companies.
- The MFDS is expected to reach an agreement with Switzerland for the mutual recognition of good manufacturing practice (GMP) inspections in the second half of 2018. The ministry will seek further mutual recognition agreements with other European countries, which will help both importers and exporters by eliminating the need for a foreign agency to inspect manufacturing plants.
- South Korea continues to climb the global rankings in terms of its attractiveness as a clinical trial site. Efforts are being made to improve capabilities in early-stage trials.
- Serialization of drug packaging will be fully enforced for all stages of the distribution system from mid-2019. This will greatly improve transparency and help the authorities to root out illegal practices, such as rebates.
- There have been a number of high profile actions against illegal rebates over the past year, involving both local and foreign companies. There are signs that attitudes are changing, with companies introducing codes of conduct to drive out illegal practices within their organizations.
- The introduction of patent linkage does not appear to have caused significant delays to generic launches. The renegotiation of the US-Korea Free Trade Agreement (KORUS FTA) will provide an opportunity for US multinationals to push for more protection for patented products.

Pharmaceutical Business Environment

- There will be considerable growth in the healthcare market over the next few years, driven by long-term demographic and epidemiological trends and the more immediate boost from the introduction of Mooncare. However, with the NHI predicted to be operating at a deficit by 2019, drug cost-containment measures will become inevitable in the second half of the prognosis period. Mooncare will add new layers of complexity and uncertainty to the operating environment.
- The pharmaceutical industry is changing in response to government encouragement of R&D and action against illegal rebates, with the leading companies being quickest to adapt to the new environment. There is more spending on R&D for new drugs, biobetters and biosimilars, with strong growth rates in foreign markets. Celltrion and Samsung Bioepis are emerging as two of the leading biosimilar companies worldwide.

- The generics market is growing, but could be a target for price cuts if Mooncare strains the NHI budget. This would threaten the existence of many small and medium-sized generic companies.
- The number of distributors continues to grow, with most entrants being very small, geographically limited businesses. The sector will find it difficult to cope with the rise in the minimum wage and the full implementation of serialization in mid-2019, and smaller companies may have to change their business model if they are to survive.
- The retail pharmacy sector is stable but under pressure. Pharmacies are seeking a greater role in chronic disease management, but may face opposition from doctors. Pharmacies will be hit by the decision of some companies to change the status of products from OTC to functional food, in order to access bigger markets.
- The government's actions against illegal rebates have had a significant impact on sales and promotional activities. Sales reps have far less access to doctors than before, and detailing has become more science-based. The use of new technologies is being explored.

Total Market Forecasts 2018-2022

Analysis of Rebates and Discounts

Sales in Market Prognosis are reported at the ex-manufacturer price level based on invoice pricing that does not capture rebates and discounts. The following is an assessment of the extent to which discounting and rebating occurs and its potential impact on the Market Prognosis forecast for South Korea.

Sales audits for South Korea report the market at National Health Insurance (NHI) reimbursement prices for products covered by the NHI, and at the most frequent transaction price based on a mixture of wholesaler selling invoices and pharmacy purchase invoices for products not covered by the NHI. For each product form, the price used is the last list price published for the reporting period. Where discounts are higher than average, the price in the audit will be the net retailer's purchasing price used in the majority of transactions. Discounts vary widely, with average discounts estimated at around 10-15% in the hospital market and 0% in the retail market, equivalent to around 3.0-4.5% of the total market.

Market Prognosis shows sales at ex-manufacturer prices. Sales values shown do not capture discounts negotiated and the market value can therefore be overestimated.

Summary of the Prognosis

All values shown are in local currency.

IQVIA captured 99% of the total pharmaceutical market in 2017. The prognosis incorporates an estimate of the value of the unaudited sector and, for the purpose of this forecast, assumes that this will grow in line with the rest of the market and hold a market share of 1% throughout the forecast period.

The total pharmaceutical market is expected to grow at a CAGR of 4.7% ($\pm 1.5\%$) during the period 2017-2022.

Key Issues Affecting Market Growth

- The 'Moon Jae-in Care', a package of reforms unveiled in August 2017, aims to expand insurance coverage to almost all healthcare treatments and procedures by 2022, including some 480 drugs which are not currently reimbursed.
- Efforts have been stepped up to improve the pricing and reimbursement environment. Risk-Sharing Agreements (RSAs) and the May 2015 pricing reform packages will continue to increase reimbursement coverage of high-priced innovative oncology and orphan drugs, while the 7.7 Drug Price Improvement Plan will grant preferential pricing and accelerated listing to certain locally-developed innovative drugs.

- South Korea's population is aging rapidly at rates unmatched in other countries. Demographic and epidemiological trends will continue to drive growth in pharmaceutical spending – especially on the treatment of chronic age-related diseases.
- The government will continue to take concerted action against illegal rebating until it no longer plays a significant role in the healthcare market. The enforcement of the Kim Young-ran Law and the K-Sunshine Act – in September 2016 and January 2018, respectively – will continue to depress marketing and promotional activities, reducing prescribing volumes encouraged by illegal rebates.
- The biennial discount-based price cuts under the actual transaction price (ATP) system will continue to exert downward pressure on established products. The latest ATP price cut was implemented in February 2018.
- The rapidly rising NHI expenditure – in particular associated with the implementation of Mooncare – is predicted to erode the NHI financial surpluses in the short-medium term. The introduction of further cost-containment measures designed to curb pharmaceutical spending may become inevitable during the second half of the forecast period.

Change in the Prognosis

There is no significant change in the five-year outlook for South Korea compared to the previous forecast published in September 2017. However, trends in individual market sectors have changed, especially the audited retail/clinic sector. The following changes have been made to the forecast:

Baseline Changes

- **Retail/Clinic Sector:** Much stronger than anticipated volume growth in the audited retail/clinic sector in 2017 has resulted in an upward adjustment to the volume baseline projection throughout the forecast period.
- **Hospital Sector:** Much stronger than expected volume growth in the audited hospital sector in 2017 has resulted in an upward adjustment to the volume baseline projection throughout the forecast period.