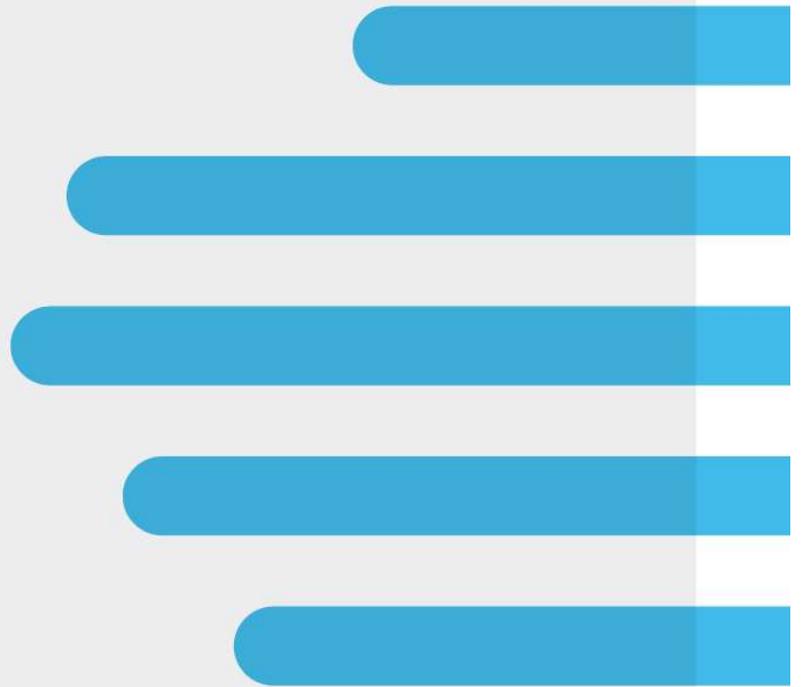


A Look into the Epidemic's Impact on Korea Healthcare

COVID-19 and more to come

March 2020



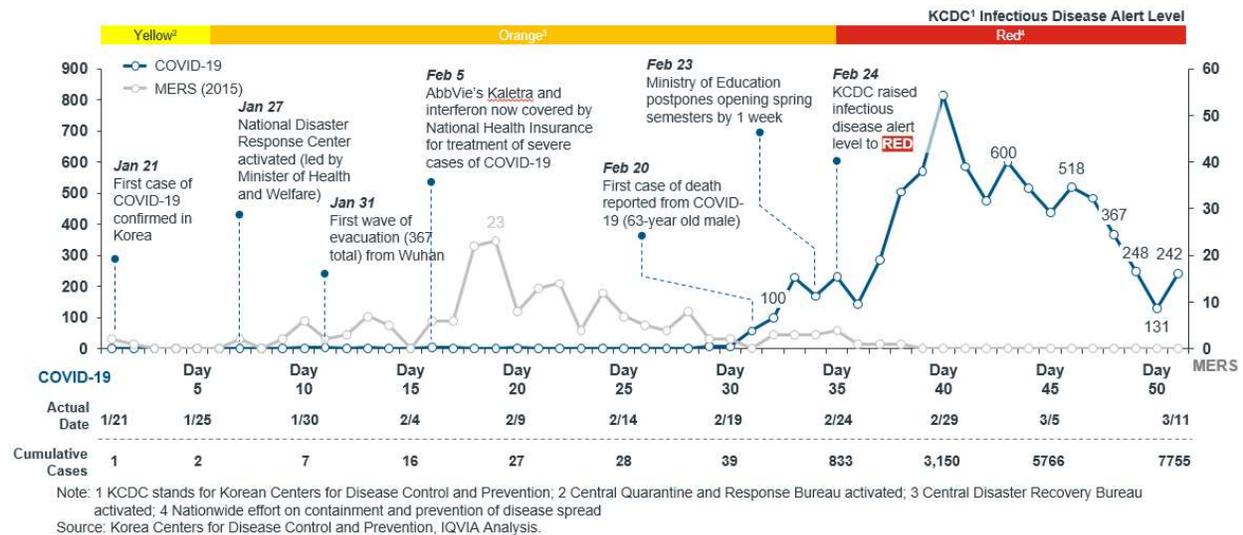
RESEARCH BACKGROUND AND OBJECTIVE

This report is intended to provide healthcare leaders with our perspective on the evolving situation of COVID-19 outbreak in South Korea and implications for their organizations and healthcare industry as a whole. This report reflects our view as of March 11, 2020.

With total confirmed cases reaching 120,000 from 117 countries as of March 11, 2020, the progress of COVID-19 situation is rapidly and severely affecting East Asia (centered in China, South Korea, and Japan), Western Europe (Centered in Italy, Spain, France, Germany), the Middle East (centered in Iran), and North America (cases arising in the United States). These countries represent well over 50% of the global economy, and the daily movements of people within and out of these countries will make it virtually impossible to contain the situation completely. Highly restrictive public health measures imposed by governments may help contain the spread (as seen in the case of Hubei province in China), but emerging cases elsewhere shed a somewhat pessimistic outlook on the possibility of community transmission.

In South Korea, COVID-19 outbreak has reached a new critical phase where decreasing numbers of newly diagnosed cases indicate that there may be positive results of the nationwide containment effort. However, it remains to be seen, whether community transmissions in various geographical areas within Korea will appear that could lead to further waves of COVID-19 spread in a near future.

Exhibit 1 Comparison of Newly Diagnosed COVID-19 and MERS (2015) Patients in Korea (Mar 11, 2020)



It is difficult to estimate the when the outbreak will completely subside. But the impact of COVID-19 on the economy certainly seems to be unavoidable. In fact, the South Korean economy is already experiencing a substantial slowdown across industrial sectors. Consumer confidence is quickly eroding, and restrictions on travel, tourism and activities that require mass gathering may even accelerate the impact on South Korean economy.

Business impacts, undoubtedly, will vary by industrial sectors. Tourism, aviation, and hospitality sectors will see lost demands that will remain irrecoverable even after the economy restarts. Lost demands in offline entertainment industry, represented by movie theaters and amusement parks, are

also obvious. During this period, however, online retailing, logistics, gaming, and online education industries will see marked growths and opportunities for business expansion. Consumer goods industry may suffer from customers delaying discretionary spending until they feel confident that the spread is well under control. Geographical variance on business impact may also be observed, as some regions that are unable to contain the spread may suffer from more severe and prolonged impact.

Exhibit 2 Impact of COVID-19 on Various Industrial Sectors



Sources: Ministry of Justice, The Credit Finance Association, IQVIA Analysis

Recovery of consumer confidence and demand return may depend on the fatality ratio. If (1) the disease's fatality ratio turns out to be lower than current statistics and those seen from other recent outbreaks, and (2) the continued growth of confirmed cases slow down, consumer demand recovery may be accelerated. If the fatality ratio proves to be on the higher side, however, the recovery of economy may be further delayed when coupled with consumer demand headwinds (which is further exacerbated by stronger restrictions on daily movements).

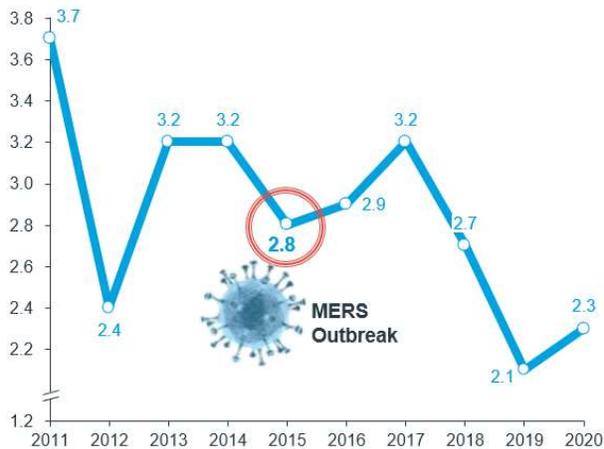
Table 1 Statistics on Recent Major Infectious Disease Outbreaks

	SARS (2002~2003)		H1N1 (2009)		MERS (2012~2015)		COVID-19 ('19.12~)	
	Global	Korea	Global	Korea	Global	Korea	Global	Korea
Confirmed Cases	8,096	3	1.63M	740K	1,545	186	130K+	7K+
Death	774	0	19K	263	588	39	5K+	60+
Mortality Rate	9.6%	0.0%	1.1%	0.035%	38.1	20.9%	3.6%	0.8%

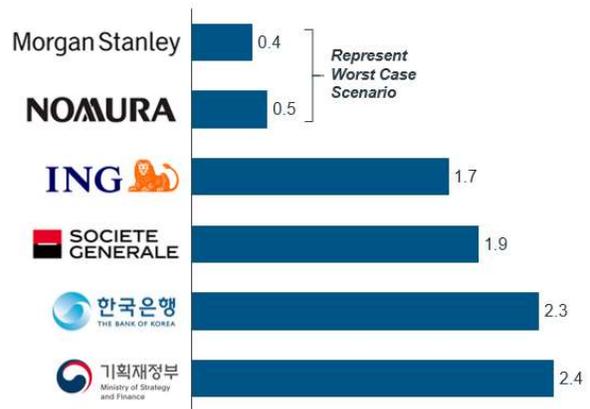
A significant slowdown on GDP growth is expected as industries strive to weather the storm. We have seen predictions as low as 0.4% GDP growth by leading financial institutions (forecast based on the worst-case scenario), much lower than the 2.3% predicted by the Bank of Korea prior to COVID-19 outbreak. While the actual growth rate remains to be seen, South Korea has experienced a similar case during MERS outbreak in 2015, where the growth rate was reduced by 0.4%p. As stated before, the path to recovery and economic restart will heavily depend on the pace of confirmed case growth.

Exhibit 3 Impact of COVID-19 on South Korean GDP Growth

COVID-19 Impact on S. Korea GDP Growth
% Growth YoY



2020 GDP Growth Forecast
% Growth YoY



Source: Ministry of Strategy and Finance, The Bank of Korea, Morgan Stanley, Nomura Securities, ING, Société General

In the following sections, we will discuss the results of our study on **the impact of COVID-19 on South Korean pharmaceutical industry**. Our study features first-hand testimonials and survey results from key players in the industry, which we believe will provide a comprehensive overview of the market response to the recent outbreak.

We will also present our **perspective on drug development and clinical testing** where countermeasures against current challenges will be ignited by the need for rapid response to disease outbreaks such as COVID-19.

Lastly, we will discuss **how COVID-19 has and will fundamentally change** the way the society - government, industry, and the public - **responds to weather the storm and remain sustainable**.

IMPACT OF COVID-19 ON KOREAN PHARMACEUTICAL MARKET

Research/Analysis Methodology

IQVIA Korea's Thought Leadership Team conducted in-depth research on short-to-long term effect of COVID-19 outbreak on Korean pharmaceutical market, using the following primary data:

- Analysis of IQVIA KPA raw data and Consumer Health sample data
- Online survey on IQVIA MEDIBUS panel (274 pharmacist participants)
- Phone interviews with managers at 11 medium-to-large drug wholesalers
- Comparative analysis using IQVIA China's perspective on COVID-19 impacts

We used the collected data and used IQVIA's proprietary Market Prognosis model to draw implications of COVID-19 on the Korean pharmaceutical market, conducting analysis on overall market forecast and detailed studies on TA/channel/geography-specific insights.

Key Findings

IQVIA Korea predicts that COVID-19 will have both direct and indirect impacts on Korean pharmaceutical market in 2020, which adjusts our predicted 2020 growth rate from 8.6% to 4.4%. We anticipate that the market will start to recover in the second half of 2020, with full recovery expected in 2021.

Looking back, Korean pharmaceutical market in 2019 showed a marked growth, 2%p higher than the average of previous 5 years. Prior to COVID-19 outbreak, we anticipated that a similar level of growth in 2020 as well (approximately 2%p higher than our prediction from IQVIA Market Prognosis in 3Q 2019). However, we now predict that the growth will be reduced to 4.4% (approximately -7%p in 1H 2020 and -1% in 2H 2020 vs. previous forecast). This translates into over 800 billion KRW impact on Korean pharmaceutical market.

Key drivers to this significantly reduced growth in Korean pharmaceutical (and healthcare) market include (1) lockdown of local hospitals in specific geographic areas, (2) a sharp decrease in patients' hospital visits due to public fear on spread of disease, (3) a substantial downturn in economic activities that lead to less overall demand on healthcare services. All of these could result in a substantial economic burden on Korean government, which could lead to shifts in national health insurance policies and initiatives to cut drug prices, further contributing to the negative impact of COVID-19 on Korean pharmaceutical market.

Significantly limited sales and marketing activities by medical representatives and delays in direct communications through face-to-face meetings could contribute to less favorable results in hospitals' procurement decisions. Many pharmaceutical companies are now under work-from-home policy, and an increasing number of hospitals are not allowing hospital visits by medical representatives. We anticipate that this trend will continue for some time, and market changes (i.e. new product launch) that require significant sales and marketing efforts will be severely limited.

IQVIA defines the end of a disease outbreak as the point at which no new confirmed cases of the disease have been observed for 28 days. With confirmed cases of community transmissions still

emerging in various geographic parts of the country, it is still difficult to accurately predict when and how this outbreak will end. We anticipate that such point for COVID-19 may occur in 3Q 2020 or later; its impact on pharmaceutical industry, however, may be limited once a clear indication of decreasing number of new confirmed cases and predictability of disease spread come under control.

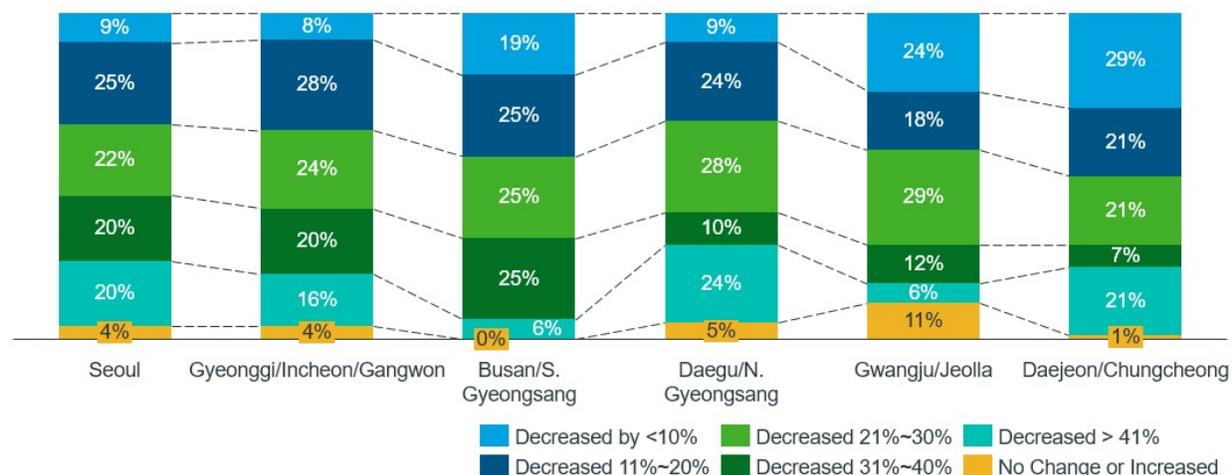
Analysis of IQVIA Korea’s pharmacy sales data from January 2020 shows a year-over-year growth of 3.4% and month-over-month growth of 5.5%. Considering that the Lunar New Year holidays fell on January in 2020 unlike previous year, the impact of COVID-19 on pharmacy sales appears to be rather insignificant.

A considerable impact appeared in mid-February, and we predict that there will be more than 10% decrease in pharmaceutical sales value throughout the country. We observed a clear downward trend in patient visits to hospitals, as well as a strong linkage to decreasing number of prescriptions and a sharp downturn in drug wholesalers’ revenues.

Impact of COVID-19 Pharmaceutical Market – by Distribution Channels and Prescription Types

Our analysis of the outpatient prescription market, which is the largest share of total pharmaceutical market in Korea, indicates that approximately 23% reduction in outpatient prescription is expected post-COVID-19 outbreak. We did not observe any statistically significant differences in responses from our panels in Seoul, Daegu/N. Gyeongsang, and other regions. However, pharmacists in Gwangju/Jeolla area had higher percentage of “No Change or Increased” responses compared to other regions (12% compared to 4% total average), and lower percentage of “Over 30% decrease” response compared to other regions (18% compared to 34% total average). This implies that Gwangju/Jeolla region did not see much impact from COVID-19. There were no statistically significant differences among responses based on (1) the size of pharmacies that participated in the survey (one pharmacist/two or more pharmacists) or (2) ownership of the pharmacy (pharmacist owns the pharmacy/hired by another pharmacist).

Exhibit 4 Changes in Hospital Outpatient Prescriptions Since COVID-19 Outbreak - by Region



According to the results of our phone interviews with 11 drug wholesalers (conducted on February 27, 2020), an average of 13% decrease in wholesaler revenue was expected during the period of COVID-19 outbreak (minimum of 8% and maximum of 30%).

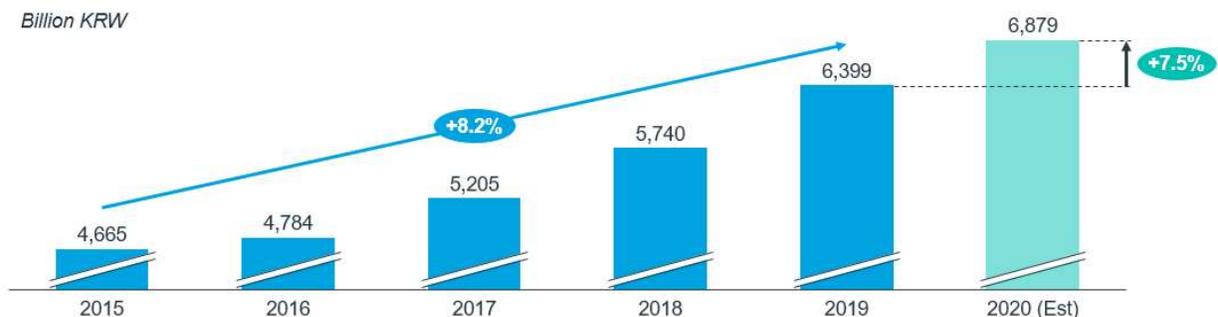
Interviews with healthcare industry experts indicate that a sharp decrease in outpatient prescription market is mainly attributable to decreased number of hospital visits by patients. Our respondents testified that while only 5% decrease in outpatient visits to hospitals and clinics was observed in early February 2020, a 20~30% decrease was observed after February 19. While the number varies among departments within hospitals, such range was also observed among drug wholesalers, medical representatives, and doctors at local clinics.

Pharmacists felt that the decrease on their sales due to COVID-19 was on average 10% lower than those felt by drug wholesalers. A substantial number of our pharmacist panels responded that their sales would decrease by 41% or more, which signifies that pharmacists who are the point of contact with customers may suffer from a more significant impact. One explanation to this result is that the duration of each prescription may be longer (because patients do not visit hospitals as often), leading to the number of prescriptions disproportionately decreasing compared to total drug consumption.

Impact of COVID-19 on Hospital Inpatient Market

During the past 5 years, the hospital inpatient market in Korea has grown at an average of 8.2% per year. President Moon Jae-in's plan, dubbed "Moon Care", will be implemented in stages throughout 2022 and pledges to expand healthcare coverage to cover 70% of the people's costs. Large general hospitals are likely to benefit from the Moon Care – in 2019, the national hospital inpatient market has grown 11% primarily due to volume-driven growth.

Exhibit 5 Korean Pharmaceutical Market 2015~2020 - Hospital Inpatient



As of February 2020, we have not observed significant changes in the prescription and purchase patterns in hospitals (including biddings from drug wholesalers); but we anticipate that a reduced 7.5% growth in 2020, primarily due to the lack of resources in within hospitals responding to COVID-19 spread and limitations on collaboration among hospitals to reduce the risk for disease spread between hospitals.

In contrast to outpatient prescription market, the number of outpatients will suffer from a sharp downturn. We also predict that the number of inpatients will not decrease as fast. Our data shows that during the third week of February 2020, there was a 5% decrease in the number of outpatients compared to the previous week – during the fourth week, the number dropped by 30%. The number of inpatients has not shown to be changing at a significant level during the same period.

Limitations in sales and marketing activities, including direct communication between HCPs and pharmaceutical companies, will negatively affect hospital's purchasing patterns. Many pharmaceutical companies have implemented work-from-home policy as of March 2020 and increasing number of hospitals are prohibiting hospitals visits by medical representatives in order to minimize the risk of

disease spread. We anticipate that this trend will continue until a clear indication of COVID-19 spread slowing down is observed. Until then, business initiatives that require strong support from sales function (i.e. new product launch or large-scale procurement by hospitals) will be substantially limited.

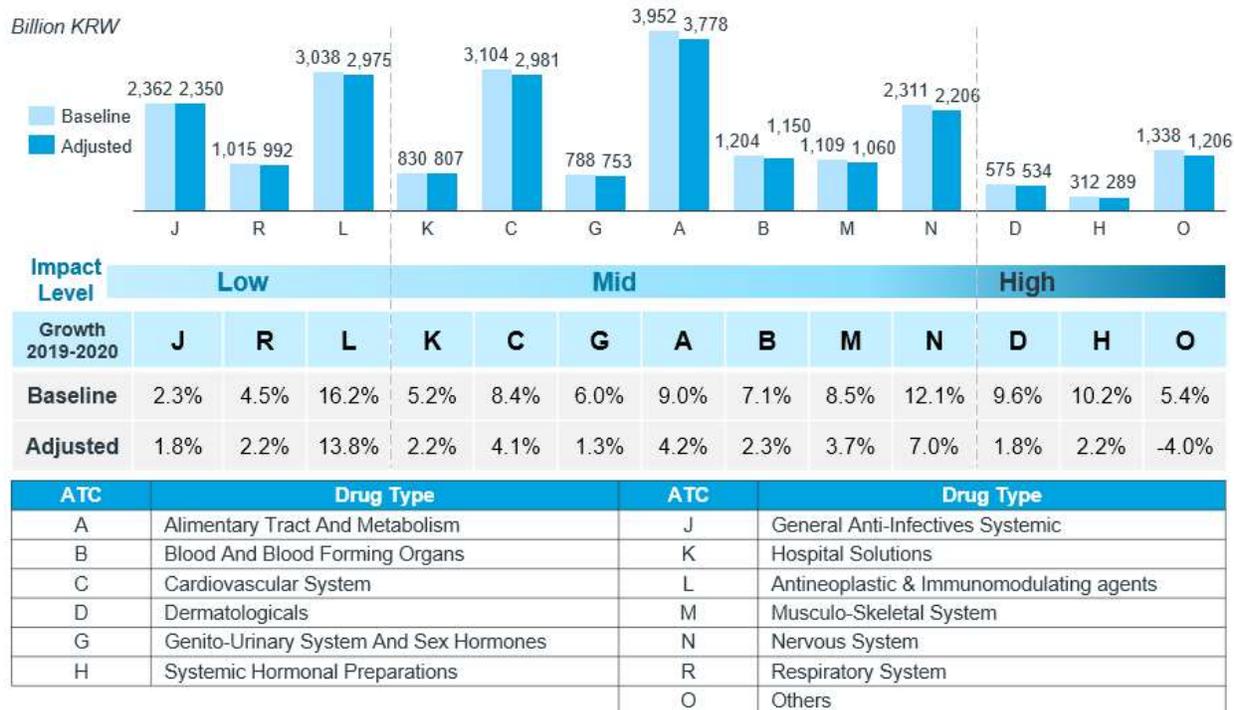
Impact of COVID-19 Pharmaceutical Market – Analysis by TA

We expect to see a high degree of variance in impact on sales values by drug types for the following reasons:

- Different patient behaviors based on their diseases and symptoms
- Changes in sales value for drugs related to COVID-19
- Geographical differences in sales values for certain class of drugs (i.e. Seoul/Gyeonggi area's market share on anticancer drug is nearly 64% of total sales)

Drug types that we predict to be least affected by the COVID-19 outbreak include antiviral agents (Class J – general anti-infectives), respiratory drugs (Class R – respiratory system), and drugs for life-threatening conditions (Class L – antineoplastic & immunomodulating agents). We predict that drugs for chronic diseases (i.e. hypertension or diabetes) and categories with high share of outpatient sales will be moderately affected by the outbreak. Lastly, adjuvant drugs are going to be strongly affected, as patients with non-urgent diseases will be less likely to visit hospitals for prescriptions.

Exhibit 6 Korean Pharmaceutical Sales Forecast in 2022 - by Drug Type



COVID-19 Impact on Korean Pharmaceutical Market – Comparative Analysis with Chinese Market Prognosis

To bring an additional perspective on the market prognosis, we refer to a similar study conducted in China which experienced the outbreak approximately one month ahead of South Korea. IQVIA China’s research based on Market Prognosis model indicates that the COVID-19 outbreak is predicted to drive a minimum of 2.4% reduction in ex-Hubei pharmaceutical market growth for 2020. Not surprisingly, the impact of COVID-19 vary substantially by different geographic regions within China.

There are over 70,000 confirmed cases of patients in Hubei province, representing over 0.1% of total provincial population. Highly restrictive public health measures imposed by the government, along with serial lockdowns of local hospitals, put a significant strain on economic activities within the region. Widely regarded as the area with most severe COVID-19 impacts, relevant statistics in the Hubei province (including confirmed cases and fatality ratio) is in striking comparison with other Chinese territories.

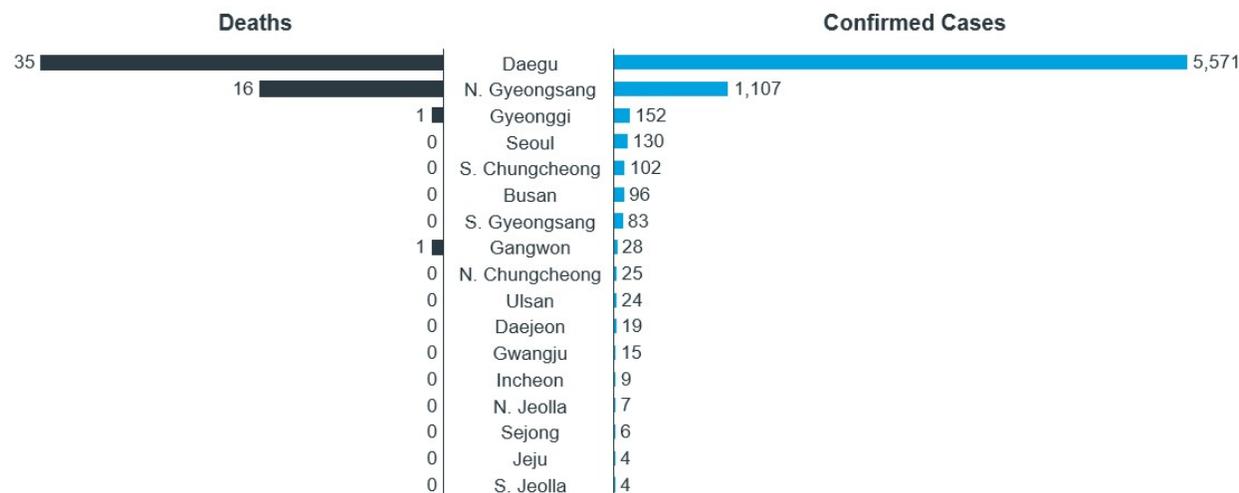
Our research predicts that pharmaceutical market in Hubei will suffer from over 28% reduction in terms of sales value and its path to recovery will be much slower than the rest of China, with its impact lasting until the end of 2020. It is rather fortunate, however, that Hubei’s market share is less than 5% of total Chinese pharmaceutical market; pharmaceutical companies may be able to accelerate their recovery through post-outbreak demand surge in the second half of 2020.

Looking at quarterly outlooks of the entire Chinese pharmaceutical market from our Market Prognosis model, a minimum of 6% reduction in sales value is expected in Q1 2020. Recovery is predicted to take nearly 3 months, leading to a minimum of 3% reduction in sales value in Q2. Full recovery is expected in 2021.

Impact of COVID-19 on Korean Pharmaceutical Market by Region

With over 90% of confirmed cases and 96% of deaths, Daegu/North Gyeongsang area represents the center of transmission complex in South Korea. Confirmed cases in other areas, including Busan/South Gyeongsang, Seoul/Gyeonggi, and Cheonan are mostly small-scale cluster transmissions. Cases in Jeolla, North Chungcheong, Gangwon, and Jeju are quite rare.

Exhibit 7 COVID-19 in South Korea - Confirmed Cases and Deaths



Such geographic variance will result in a strong short-term negative impact on pharmaceutical market in Daegu/North Gyeongsang area, where HCPs are primarily concentrating on virus-curbing effort to fight off further spread of disease. With hospital lockdowns and the public's fear on disease spread already prevalent in the area, hospital/clinic visits by patients will be greatly reduced as well as pharmacy visits. The number of confirmed cases per million people in Daegu/North Gyeongsang area has reached a level similar to that of Hubei province, alluding to a dim outlook on economic recovery even after the COVID-19 spread subsides within the region; we expect that full recovery of pharmaceutical market in Daegu/North Gyeongsang area will take 2~3 months longer than other regions in South Korea.

From disease type perspective, the pharmaceutical market in Daegu/North Gyeongsang area, where the market share of L-class (such as anticancer drugs) is not as high as other areas (approximately 8.5% of total sales value), will suffer heavily from COVID-19 outbreak; we expect approximately 25% reduction in sales value. Due to this impact, we predict that Q1 2020 and Q2 2020 sales value in Daegu/North Gyeongsang area will be substantially lower than previous year. We expect that such outlook will have an impact on the national sales value forecast as well, as the market share of Daegu/North Gyeongsang in overall Korean pharmaceutical market is approximately 10%, twice the size of the market share held by Hubei province in China.

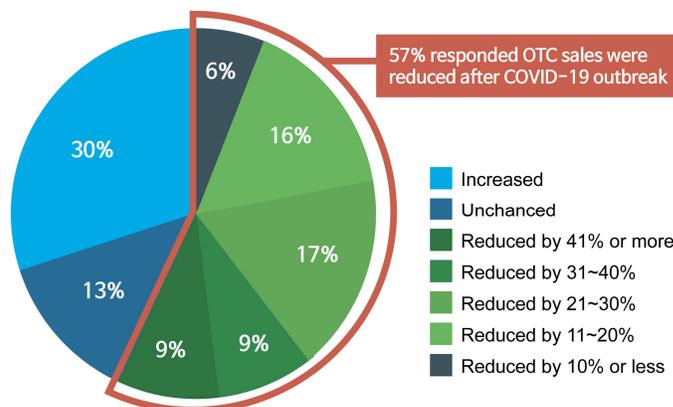
Our analysis shows that the overall impact on Korean pharmaceutical market is likely to be different from the case in China, resulting in a nationwide impact that will be felt much stronger in a prolonged manner. Extraordinary public health measures including travel restrictions in and out of Daegu/North Gyeongsang area is not likely to be imposed, and the first wave of spread centered around the Shincheonji Church of Jesus (a minor, secretive Christian sect strongly linked to the COVID-19 outbreak in Korea) may see subsequent waves on a national scale. There are well over 200 confirmed cases in Seoul/Gyeonggi area, with numerous cases of community transmissions and individual cases that are difficult to track down epidemiologically.

Ongoing public health measures to relieve the burden on Daegu/North Gyeongsang area include reallocation of medical resources (medical personnel and consumables) and transfer of patients in Daegu/North Gyeongsang area to other areas with better access to medical care. These efforts, which contrasts with Hubei-specific impacts seen in China, will have a stronger impact in overall Korean pharmaceutical market. Time to recovery in this region, owing to massive degree of impact COVID-19 had on local economy, will be substantially longer than the rest of Korea. The result of an online survey that we conducted on our pharmacist panel strongly aligns with our forecast.

Impact of COVID-19 on OTC Sales

Results from our online survey on OTC sales showed somewhat confounding responses. While 57% of our respondents replied that OTC sales were reduced since the outbreak, 30% said that their OTC sales increased during the same period. For those who responded that their OTC sales decreased, it is possible to hypothesize that the result was due to overall decrease in patient visits to pharmacy (responses to other questions in the survey indicated that 63% of the participants said their overall sales decreased during the said period). For the group that responded their OTC sales increased, 59% of those respondents said that OTC drugs for common cold, cough and antipyretics showed marked growth in sales.

Exhibit 8 Impact of COVID-19 on OTC Sales in Pharmacy - Survey Results



Vitamins, a major contributor to OTC sales at local pharmacies, show interesting patterns - results from our survey showed mixed opinions from pharmacists. While IQVIA Korea’s sales data from drug wholesalers and pharmacies on vitamin sales show a marked increase during the recent outbreak, our pharmacist respondents had mixed opinions on the sales pattern. The reason for such varying responses could be attributed to different vitamin sales value for each pharmacy.

However, the reason behind an overall increase of vitamin sales could be due to what the general public has learned from MERS outbreak in 2015, where medical experts claimed that vitamin C helps preventing the disease. Other well-known health supplements and vitamin products (i.e. Korea Undan with vitamin C) recorded sold-outs in many pharmacies across the country, but only had a temporary effect in the overall vitamin market. It is also interesting to note that Yuhan’s Antiplamine (anti-inflammatory ointment) was rumored to be effective on coronavirus infection, which led a surge in demand, but it did not last long enough to be considered as a significant trend.

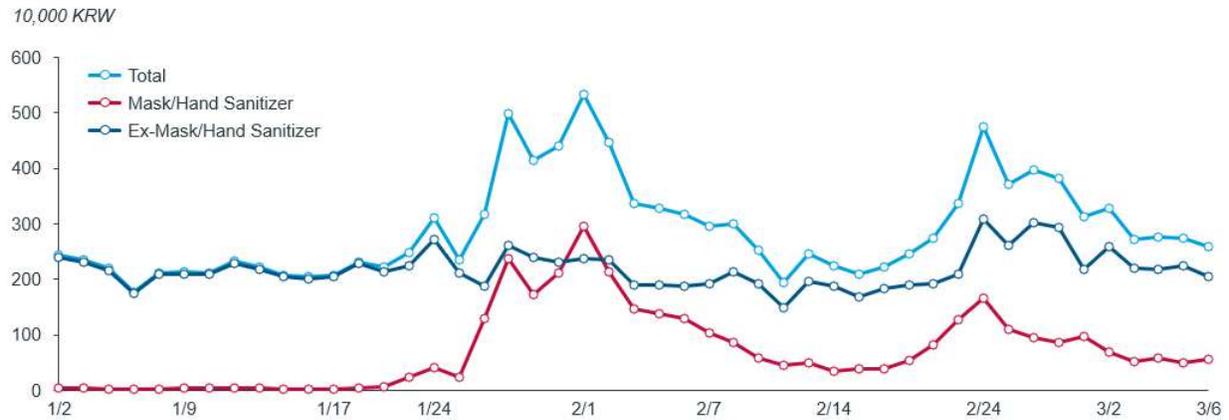
Sales Trends on Medical Consumables Including Masks and Hand Sanitizers

IQVIA Korea’s data on pharmacy sales for medical consumables including masks and hand sanitizers indicate that there is not significant change in sales patterns in early January. It is interesting to notice that pharmacy sales in January increased in comparison to results from previous years – we believe that it is due to increased sales in these medical consumables.

The portion of masks/hand sanitizers in total pharmacy sales started increasing in January 20 when the first case of COVID-19 was confirmed in South Korea. Then starting January 24, mask/hand sanitizer sales, along with total pharmacy sales value, started to soar as the second confirmed case of COVID-19 was identified. The trend continued until January 31 when mask/hand sanitizer sales starts to decrease along with total pharmacy sales, indicating that consumers have temporarily regained confidence in public health measure as the number of newly diagnosed cases decreased.

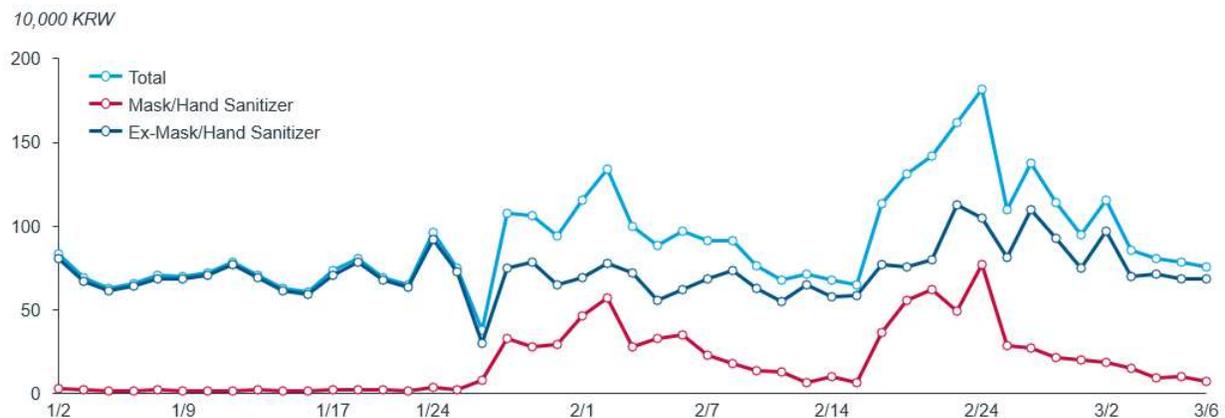
The first case of Shincheonji-related case (case No. 31 overall) appeared in February 18, and this sparked a sharp increase in mask/hand sanitizer sales. The portion of mask/hand sanitizer has also increased. Such pattern is more apparent in Daegu area, where the share of these items took nearly 30% of total pharmacy sales, compared to less than 1% in January 2020.

Exhibit 9 Trends for COVID-19 Consumables vs. Total Sales (Average Value for National Top 100 Pharmacies)



Close observation into data from Daegu area reveals that sales records for items other than face masks and hand sanitizers are also increasing, which can be attributed to an increase of purchase for other items including common cold/cough medication, immune boosting supplements, and painkillers. This indicates a possibility of panic buying within the region.

Exhibit 10 Trends for COVID-19 Consumables vs. Total Sales (Average Value for Top 20 Pharmacies in Daegu)

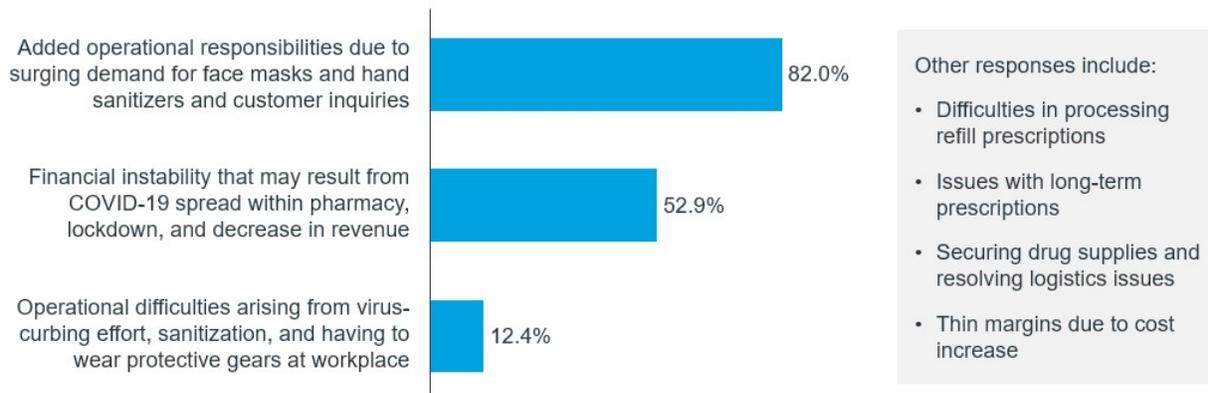


Other Challenges Faced by Pharmacies and Drug Wholesalers

Lastly, we asked our pharmacist panels on impacts of COVID-19 outbreak on their daily pharmacy operations. Nearly 82% of respondents agreed that the surging demand for masks and hand sanitizers is causing serious bottlenecks in pharmacy operations, with more time being spent on securing sufficient inventory of those items and responding to customer inquiries. In addition, nearly 53% of respondents had concerns about financial instability that could be caused by decreased revenue from pharmacy lockdowns and COVID-19 spread at their workplace. Operational difficulties arising from virus-curbing effort, extra sanitization, and having to wear protective gears at workplace reported to have impacts on pharmacy operations. Other responses included difficulties in processing refill prescriptions, issues in dealing with patients with long-term prescriptions, securing drug supplies and resolving logistics issues, and thinning margins due to cost increases.

Exhibit 11 Impact of COVID-19 on Pharmacy Operations

n = 247, multiple responses are accepted



Drug Distribution and Manufacturing

In a statement made February 27, 2020, US FDA Commissioner Stephen Hahn announced that a drug manufacturer had alerted the agency to the shortage of a drug that had been added to the drug shortages list, indirectly indicating that the shortage was indeed due to coronavirus. While the drug in question has not been identified, Hahn mentioned that the shortage is due to an issue with manufacturing of an active pharmaceutical ingredient used in the drug. The agency has been in contact with more than 180 pharmaceutical companies and has asked them to evaluate their supply chains, including active pharmaceutical ingredients and other components that are made in China.

In the case of South Korea, we have not seen the impact on the supply and distribution of imported drugs yet. The situation may shift, however, if the outbreak develops into a global pandemic that has a significant impact on worldwide logistics. We highlight below potential short-term implications to a continued spread of COVID-19 in East Asia:

- Even for drugs manufactured in Korea, pharmaceutical companies rely heavily on active pharmaceutical ingredients originating from China, presenting a high potential risk on supply chains. However, Wuhan is primarily known for being the hub of modern manufacturing (automotive and steel) and high-tech industries (opto-electronic, biological engineering, and environmental engineering), and less so as the center of pharmaceutical industry. Therefore, we speculate that the impact of COVID-19 outbreak on drug manufacturing industry's supply chains may be limited unless subsequent waves of disease spreads affect other parts of China.
- There are growing concerns on securing sufficient medical consumables (such as disposable gloves and masks) at local hospitals, absolute majority of which come from China. Many hospitals are already experiencing difficulties in managing supply chains for these consumables, and extra cost may incur if they plan to meet demands in clinical settings. Smaller hospitals that are unable to diversify supply chains and keep inventory levels in a timely manner may suffer from bigger impacts.

CHALLENGES AND COUNTERMEASURES FOR DRUG RESEARCH AND DEVELOPMENT

The fast-spreading COVID-19 outbreak is starting to disrupt clinical trials, which could pose a threat to plans set by pharmaceutical companies to harness the potential of Asian countries in the race to get drug molecules into the market. Virus-curbing efforts by hospitals are making it difficult for trial patients to reach hospitals, and lack of medical resources are delaying the launch of new studies, while CROs are unable to send staff to monitor trial sites. Countermeasures to minimize such impacts are being investigated, both to ensure successful completion of ongoing trials and to introduce digital transformation in clinical trials. To this end, government support in regulatory processes and establishing “virtual clinical trial” platform is crucial to success, and countries like China are getting ahead in competition.

Experimental treatment of COVID-19 with existing drug molecules and development of new antiviral drug molecules are also under way. Compassionate drug use and post-market re-evaluation are both being considered, with pharmaceuticals and biotech companies at different phases of R&D. In this section, we will highlight some of the ongoing efforts by both multinational and local companies.

Impact on Clinical Development

Clinical development operations are likely to suffer from COVID-19 outbreak, with interruptions in ongoing clinical trials and delay of new trials due to the following reasons:

- **Scarcity of clinical trial-related resources.** Overall patient visits to hospital expected to be reduced especially for less serious illnesses. Also, a high number of site initiation visits (ca. 50% of Q1 planned visits) are delayed while start-up process in hospitals does not have significant impact except in sites in the Daegu/North Gyeongsang area.
- **Limited principal investigators’ capacity.** Principal investigators with specialties in respiratory diseases, infectious diseases and those working in ICUs are fully dedicated to responding to COVID-19. Investigators in infection-related diseases (i.e. cardiovascular, renal, urology) also need to allocate resources to nationwide diagnostics effort.
- **Patients’ fear of potential infection.** Overall patient visits to hospital expected to be reduced especially for less serious illnesses. Potential patients for subject recruitment are less willing to participate in clinical trials. Enrolled patients in the Daegu/North Gyeongsang area had limitations in site visits due to virus-curbing efforts by the sites in Seoul or patients’ fear of potential COVID-19 infection.
- **Interruption of on-site work.** Some on-site works are pending (i.e. face-to-face communication and meetings, on-site trial monitoring, visit rearrangement for patients in the Daegu/North Gyeongsang area)

Limitations mentioned above may potentially have negative impacts on ongoing clinical trials in terms of both project management perspective (i.e. timeline) as well as quality of studies.

- **Timeline delay.** Trials in the planning phase are closed/suspended/postponed. Administrative processes involving face-to-face communications are delayed (such as committee meetings, ethics committee review meetings/voting, kick-off meetings). Administrative processes

involving paper work are expected to undergo severe delays (such as ethics committee materials, contracts, trial initiation documents).

- **Quality of study.** Patient follow-up activities (such as drug delivery, regular check-up, data recording and report) are facing hurdles, and the trial monitoring efficiency is greatly reduced

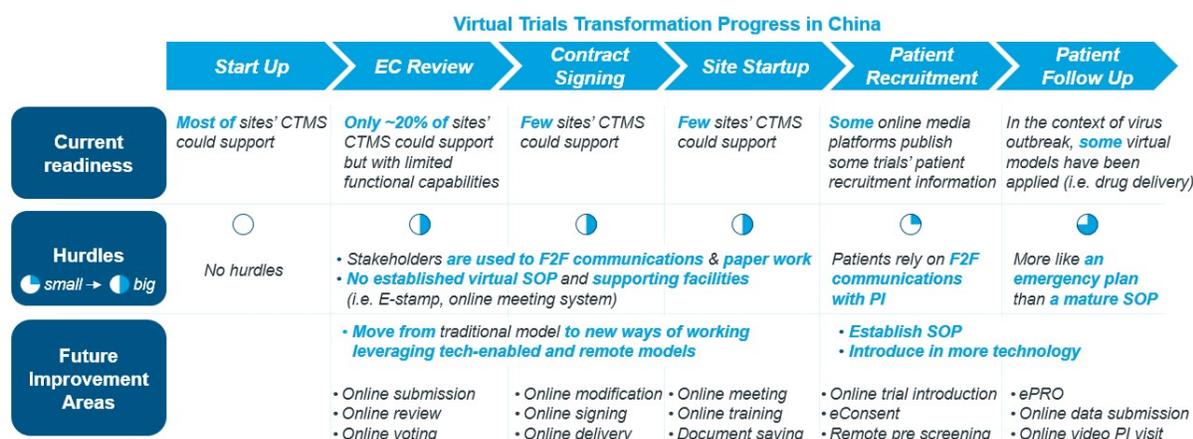
As a short-term remedy, the following steps by pharmaceutical companies and CROs are required:

- Form a COVID-19 emergency management team and establish guidelines for conducting clinical trials in the context of infectious disease outbreak (i.e. minimize or eliminate site visits for employee safety)
- Identify existing and potential challenges in development activities (i.e. delay in project timeline, insufficient trial quality monitoring) and establish countermeasures (i.e. establish remote follow-up protocol for ongoing trials)
- Consider cross-site transfer among patients participating in clinical trials.
- Evaluate the feasibility of utilizing telemedicine and direct-to-patient, where phone-based prescription is used to patients who are unable to visit hospitals, and prescription drugs are delivered to patients through courier service. The Ministry of Food and Drug Safety (MFDS) has temporarily approved the use of these options in special cases where traditional clinical trial methodologies cannot be used.

In the mid-to-long term, it would be crucial to accelerate the roll-out and scale-up of digital transformation of internal R&D (i.e. online platform/system establishment, remote trial management SOP establishment). This requires support from the government and trial sites to establish online trial management platforms, such as remote source data verification (rSDV). Legal and regulatory issues still dictate the development of such platforms, however; current Medical Service Act and Personal Information Protection Act (PIPA) stipulate that such platforms cannot be used in practice.

In China, both the government and governing authority on clinical research are strong advocates of transformation into “virtual clinical trials”, where digital technologies are leveraged at each and every step of the clinical trial process (Exhibit 4).

Exhibit 12 Virtual Clinical Trials in China - Current and Future



Experimental Treatment and Development of New Antiviral Molecules

Experimental Treatment for COVID-19

As there are no US FDA-approved vaccines or therapies for COVID-19, pharmaceutical companies are stepping forward with plans to develop treatments that target the viral infection.

Gilead Sciences has commenced Phase III clinical trials of its investigational antiviral drug, remdesivir, for the treatment of COVID-19 in adults. This announcement comes after the US FDA accepted and reviewed the company's investigational new drug (IND) application for remdesivir in this indication. The randomized, open-label, multi-center studies will assess the safety and efficacy of the drug in nearly 120 patients. A five-day and ten-day dosing regimen of an intravenous formulation of remdesivir will be tested. The trials will be conducted at sites impacted by the coronavirus outbreak, including the Seoul Medical Center, the National Medical Center, and Kyungpook National University Hospital. MFDS approved the trial within 7 days of submission of test plan by Gilead, showing the urgency of the Korean government in fighting against the disease.

MFDS is also considering Fujifilm's Avigan (favipiravir, anti-influenza drug) for clinical trial. Currently not approved by the Ministry to be administered in Korea, the agency is investigating the feasibility of applying an exception to the drug's status. Meanwhile, the Health Insurance Review and Assessment (HIRA) Service of Korea is collaborating with multinational pharmaceutical companies to ensure sufficient supply of drugs for experimental treatment of COVID-19 (i.e. Kaletra by AbbVie, Zanamivir by GSK, interferon by Roche, Merck, Bayer).

Korean pharmaceutical companies and biotechs are also at the R&D phase for drugs and vaccines against COVID-19, and we highlight a few examples below:

- Komipharm has applied for Phase II and III clinical trials of Panaphix (cytokine storm inhibitor) for its use against COVID-19 on 100 confirmed patients. However, approval by MFDS may take longer than in the case for Gilead's remdesivir, as further risk-benefit analysis and supporting data on safety and efficacy may be required.
- Celltrion secured blood sample from confirmed COVID-19 patients and began research for drug candidate molecule. The company has previously developed MERS drug candidate CT-P38 (preclinical) and will launch a separate research to investigate the possibility of using the candidate molecule in treatment of COVID-19.
- SK Biosciences and GC Pharma are currently at the R&D phase for vaccine development platform and applied to the project funded by the Korea Center for Disease Control and Prevention (KCDC) entitled "Development of Immunogenic Antigen Against 2019-nCoV".

However, one should be reminded that the most crucial aspect of successful drug/vaccine development is ensuring that the outcomes of these research efforts are strongly aligned with the KFDA's main agenda, which is safety. A series of recent incidents regarding the safety of drugs that the agency has previously approved, including Hanmi Pharmaceutical's Olita (olmutinib, lung cancer), Kolon Life Science's Invossa (osteoarthritis gene therapy), and Valsartan, forced the agency to put more stress on drug safety. To this end, MFDS is enforcing changes in regulatory processes that include (1) inclusion of new safety requirements in the mission for the Committee for Development of Clinical Trials, and (2) all monitoring reports to be submitted in the case of a suspected unexpected serious adverse reaction (SUSAR) that causes death of a patient in the clinical trial.

Given the “seriousness” of the current COVID-19 outbreak (which may be represented by the fatality ratios), the MFDS may be reluctant to approve clinical trials for drugs that were previously approved for other indications. It is possible that the agency may take its time to observe how agencies at other countries respond. As for Gilead’s remdesivir, however, it may be possible to administer the drug through treatment IND under compassionate use mechanism. In this case, MFDS would be more willing to approve, especially if the trial was to be done on a limited number of patients in potentially critical conditions.

COPING WITH COVID-19 OUTBREAK - RISK MANAGEMENT PERSPECTIVES

Business leaders must be on alert for the latest situation on COVID-19 outbreak and be prepared with various business scenarios based on the most up-to-date information as well as highly articulate predictions on how the situation may unfold. At the same time, they need to be able to evaluate policies and virus-curbing efforts made by different countries around the world, along with political and diplomatic impacts that may have direct and indirect effects on the business. That way, businesses can remain sustainable to weather the storm and be ready to jump start once again when the outbreak subsides, and the stage is set for a full rebound.

However, we believe that healthcare leaders should look beyond cost controls of their businesses or efficient operation of ongoing clinical trials and approach the situation from a long-term risk management perspective instead.

Ever since the first case of COVID-19 has been reported, scientists, healthcare providers, and governments around the world have worked together to investigate the impact of this outbreak and come up with response strategies. Lessons that we learned from recent outbreaks, including MERS and SARS were in great use – it's likely that what we learn from COVID-19 will be of great importance for the next wave of infectious disease outbreak, which may emerge when we least expect it.

COVID-19 is now widely accepted as a zoonotic disease, and like MERS and SARS, it belongs to a new type of infectious disease that can rapidly spread across the globe. These diseases are believed to be transmitted not from common livestock, but from wild animals including bats and camels. There are different ideas on the origins of these infectious agents, but it is clear that there is a very high chance of having yet another worldwide infectious disease outbreak like COVID-19 – we just don't know when.

The last section of this report covers our perspective on how businesses should be prepared for the “next COVID-19”, along with key questions to which we believe require serious thoughts.

Challenges Brought by COVID-19 and Potential Solutions

Changes in Workplace Culture by Work-From-Home Policy

Nationwide spread of COVID-19 and increasing cases of community transmissions forced businesses across industrial sectors to adopt Work-From-Home (WFH) policy. Completely different from the “traditional” employment type, WFH policy initially has sparked heated debates on its feasibility and efficiency. As more companies are adopting WFH, we're already seeing workers who have been working at home for over a month now. And both companies and employees are coming up with their own solutions to common issues such as IT and performance evaluation.

Due to the fact that Koreans traditionally have been much more inclined to have face-to-face meetings for important decision making, such transition to WFH appeared to be a tall order. Now, businesses are forced to set up virtual meetings and minimize face-to-face interactions. Indeed, COVID-19 could be a catalyst for a transition into a new way of working.

Work-From-Home is an effective solution to prevent community transmissions of COVID-19, but there is more to it than just a public health measure. People often spend up to 3 hours on their commute to and from their workplace, and WFH could be a great alternative who could make a better use of those hours. Tools like WebEx, Zoom and Skype are already there, and most multinational companies have been relying on these tools for internal communication to save on travel cost. Therefore, utilization of virtual communication tools could be a sound solution when it comes to issues on collaboration over remote settings.

Delegation of authority could pose an issue when it comes to critical decision making among employees under WFH policy. A more agile approach to this problem, such as delegating the authority at a project level instead of having several layers of management chain, could help resolve the issue.

Limited Offline Sales & Marketing Activities for Pharmaceutical Companies

Though it is due to temporary measures imposed by hospitals in response to COVID-19 outbreak, limited offline sales and marketing activities by pharmaceutical companies, if continued for more than several months, could have a strong effect on the way companies interact with HCPs.

While multi-channel marketing and digital transformation remained a key success factor for securing competitive advantages in Korean pharmaceutical industry, companies have been rather passive about making investments to implement or improve their infrastructure. This trend is due to the fact that (1) HCPs are readily accessible from geographic perspective, and (2) despite excellent IT infrastructure, physicians generally prefer traditional face-to-face meetings over communication through digital channels. We fully expect that communication through digital channels will increase and become the new norm at some point in time, but we have only seen a slower pace of transition compared to many developed countries.

COVID-19 may instigate a significant change to this trend. Pharmaceutical companies are experiencing severe limitations on their accessibility to HCPs through traditional offline channels, albeit only for a short period of time. This will lead them to consider a fundamental change in short- and long-term channel strategy. Companies will have to review their existing capabilities for multi-channel marketing (i.e. types of channels, human resources, work processes, IT infrastructure) and devise optimal channel mix strategy and manuals based on different variables and parameters (i.e. product lifecycle, competitive landscape, depth of information to be delivered, customer segmentation based on preferred channels). Companies will also have to be prepared with protocols and resources (i.e. remote detailing platform, MR training, identifying outsourcing partners) that can be put into practice once a situation like COVID-19 outbreak emerges, so that they can stay ahead of competition.

As physicians are forced to be at the receiving end of digital, multi-channel marketing by pharmaceutical companies that are more prepared than the others during the COVID-19 outbreak, we may see some changes in physicians' general attitude toward digital channels. Physicians may feel that the flexibility of digital channels has been overshadowed by their bias on preference over face-to-face communication and turn to become a strong advocate of multi-channel marketing.

Optimization of Public Health Investment

COVID-19 outbreak has caught us by surprise in 2020 – no one has ever imagined such tragedy could come to us, with growing impact on the global economy. It's already causing serious impacts across many industrial sectors including healthcare, but the magnitude of financial burden imposed

upon governments and healthcare providers can easily surpass that of a single pharmaceutical company.

As mid-to-long term response strategies to COVID-19 or any upcoming infectious diseases outbreaks, governments could consider public health measures such as additional drug price cuts or changes in national health insurance policies. Also, the fact that patients with cancer or certain chronic diseases must have access to medical services regardless of the situations at hospitals may spark the need for separate policies that accommodate these special needs (such as remote diagnosis, online prescription, refill prescriptions).

A centralized system with the “control tower” for infectious disease control could also be considered. The United States Surgeon General, the operational head of the public health system in the United States, is such an example. Such system can be at its full force when there is a serious threat to the public health system in a country, overseeing containment/quarantine strategies as well as treatment of affected individuals and allocation of relevant budgets.

Another area of investment to look into is funding research related to infectious diseases. Successful drug or vaccine development can save lives of millions or more, and a systematic and highly coordinated approach among research institutions could be liaised by the government authority. For example, enhancement of R&D infrastructure on zoonotic diseases and establishment of partnership with leading organizations such as International Vaccine Institute and Pasteur Institute could be considered.

As mentioned in the previous section on COVID-19 research, various regulatory processes could be temporarily relieved or improved to accommodate the need for rapid responses to infectious disease outbreak. Examples of such processes include (1) fast-track approval for diagnostics technologies or treatments, (2) readily accessible database of organizations with R&D or manufacturing capabilities required for drugs or diagnostics tools, (3) infrastructure that allows fast-track clinical trials of tools or drugs against disease of significant public health impact, and (4) financial support to hospitals and pharmaceutical companies participating in those clinical trials.

Epilogue

There could be numerous other negative impacts on healthcare industry that were not mentioned in this report under the worst scenario of long-lasting pandemic. One can fully anticipate a pessimistic outlook on the capital market that would lead to pharmaceuticals and biotech companies lowering their R&D investment and delays in IPOs. Travel restrictions could lead to significantly less collaboration among research organizations around the world, greatly slowing down some of the most creative research making its way into the real world. As the situation extends into the second half of 2020, its impact will be felt much stronger.

Ultimately, however, healthcare leaders will remain at the center of the stage for overcoming COVID-19 and other infectious disease outbreaks to come. Lessons learned from COVID-19, as it has been the case with all other infectious disease outbreaks, will prove to be invaluable resources for the future generation.



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