PLS & HS: The What?
Global Activity and Critical Updates at a Glance

North America
- Covid-19, a tailwind for diagnostics and medtech sector: As the number of new Covid-19 cases in the US continues to rise, the US Congress has approved an $8 billion emergency spending bill to fight the virus, partially to increase the testing kits.1
- Contract research organizations (CROs) could see headwinds if trials are delayed due to lags in patient and site selection.2
- Manufacturing disruption for active pharmaceutical ingredients (APIs) could lead to API supply shortage, and consequently generic drug price inflation (~80% of APIs come from China and India, with China being the primary source).3
- Transition to digital health models: Telehealth usage demand continues to grow amid the Covid-19 pandemic. Also, we see increase in use of AI applications to monitor the outbreak.4
- US hospitals are worried about the overcrowding emergency rooms (ERs), shortage of ICU beds, decline in elective procedures and drying up of medical supplies.5
- The US FDA has postponed foreign inspections. This will likely delay the approval of drug applications, particularly for generic drugs, given that many APIs and finished dosage forms are made overseas.6

EMEA
- European healthcare systems are not prepared for an outbreak on the scale seen in China, South Korea, and Italy.7
- Governments seek to press into service retired doctors and nurses to fill any gaps, if needed, at the height of the outbreak and encourage volunteers to help in non-clinical settings, such as care homes, by guaranteeing their jobs for a month.8
- Impact on pharmaceuticals: Short-term concern from the Covid-19 outbreak would be the impact on pharma sales in China following the partial shutdown across the country. AstraZeneca, Bayer, and Merck KGaA have the most overall sales exposure to China.4
- Chinese API impact on the European drug supply chain was modest despite heavy reliance on Asia. European pharma companies have adequate inventory levels (Brexit contingency plans), and China is not the primary source of API.
  - Global pharma giant, Sanofi (France-based), recently announced the creation of massive standalone API production facilities in Europe to balance Europe’s heavy reliance on API sourced from the Asian region.9

APAC
- Unlike other regions, ASPAC is also facing shortage of supply of medical devices like personal protective gear (PPE), staff, ICU beds, and ventilators.10
- The Chinese government’s decision of a massive shutdown in February 2020 to halt the spread of the disease emerged as a threat to global pharmaceutical supply chain.11
- The Indian government’s restriction on exports of 10 APIs/formulations in preparation of potential shortages due to supply chain linkage with China could further contribute to the likelihood of generic drug inflation.12
- Japan: Negligible impact on pharmaceuticals and healthcare. Business opportunities: Covid-19 genetic testing kits, medical equipment, and online medical consultations.13
- Australia: Healthcare facilities might see decreased volumes due to fewer elective surgeries being performed. Agency nursing costs have increased, and volumes of medical supplies, pharmaceuticals, and pathology have also increased.14

Analyst Note
- Globally, we expect to see some clear logistics (i.e., capital projects, regulatory assessment, launch, trial/development) and demand (i.e., refill/physician visits/initiations) disruption for the pharmaceutical industry overall, but relatively far less than is likely to be seen in most other industries/sectors. North America and EMEA are expected to invest significantly in API facilities to reduce their dependency on APAC.

#### Near-Term Risk Outlook, Risk Mitigation and Opportunities

<table>
<thead>
<tr>
<th>Sub-sector</th>
<th>Level of Risk</th>
<th>Near-term Risk</th>
<th>High Impact Region</th>
<th>Potential Disruptions</th>
<th>Risk Assessment</th>
<th>Opportunity Assessment</th>
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<tbody>
<tr>
<td>Biopharma Industry</td>
<td>Moderate</td>
<td>US, Europe</td>
<td></td>
<td>Drug biologic supply; New product commercialization</td>
<td>• Novel drugs’ promotion/education likely impacted by a suspension in medical meetings/conferences and fall in MR visits; this may lead to slow product uptake</td>
<td>• Vaccine businesses are likely to accelerate</td>
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<tr>
<td></td>
<td>High</td>
<td>China, India, US</td>
<td></td>
<td>Delay in product launches; Drug shortage; Increase in drug prices</td>
<td>• FDA facility inspections suspended and hence product approvals will be delayed</td>
<td>• Infectious disease categories are likely to see high R&amp;D spending and associated M&amp;A</td>
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<tr>
<td>Generic Drug Industry</td>
<td>High</td>
<td>China, India, US</td>
<td></td>
<td>Manufacturing disruption, Supply chain</td>
<td>• Big medtech players have higher exposure to China</td>
<td>• Symptomatic management (cold, flu, fever): consumer healthcare/OTC segments likely to benefit</td>
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<tr>
<td>Medical Devices</td>
<td>High</td>
<td>US, Europe</td>
<td></td>
<td>Shortage of medical supplies, emergency rooms, and ICU beds</td>
<td>• Planned investment in China might be delayed (like construction of new R&amp;D or manufacturing facility); this is also applicable to biopharma industry</td>
<td>• Short-term spike in demand for products like toilet paper, disinfectants, sanitizers, and masks</td>
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<tr>
<td>Diagnostics</td>
<td>Limited</td>
<td>Global</td>
<td></td>
<td>Shortage of medical supplies, emergency rooms, and ICU beds</td>
<td>• People may overlook routine lab testing if they are instructed to remain at home</td>
<td>• Steep increase in diagnostic demands due to sharp uptake of preventive measures</td>
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<tr>
<td>Payer/Providers</td>
<td>Moderate</td>
<td>Global</td>
<td></td>
<td>Shortage of medical supplies, emergency rooms, and ICU beds</td>
<td>• The total cost of care provided to Covid-19 affected patients should be offset by the reduction in cost from the cancellation of elective procedures</td>
<td>• Transition to digital platforms</td>
</tr>
<tr>
<td>CROs/CMOs</td>
<td>High</td>
<td>Global</td>
<td></td>
<td>Delay/suspension in clinical trials</td>
<td>• Increase in hospitalization rate</td>
<td>• Rise in online Rx or telephone consultation</td>
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</table>

Sources: Evalueserve analysis
Heavy dependency of North America and Europe on Asia for API supply may lead to shortage of drugs and drug price inflation.

- China and India are the major API suppliers for the US and Europe, and India is heavily dependent on China for APIs (70%) for its own pharmaceutical industry.
- India is a major exporter of generic drugs to the US and Europe. Generics account for more than 90% of the prescriptions dispensed in the US. Temporary suspension of Chinese API facilities is impacting India’s pharma industry, restricting the supply of generics in the overseas markets. The Indian government restricted exports of 26 APIs and products on March 3 to ensure there is no shortage of drugs in India. This may lead to shortage of essential drugs in the US and Europe. On March 2, the US reported one case of drug shortage. While drug shortage is an ongoing issue in the US, additional shortage can have a direct impact on patients’ economic, clinical, and humanistic outcomes (ECHO).

Major pharmaceuticals need to diversify their supply chain to reduce dependency on China and India.

- In response to the growing concerns about supply chain, the Indian government has introduced measures to boost local production. Similar efforts are being considered in the US. This creates a significant opportunity for volume API firms that are willing to invest in manufacturing capacity in India and the US.

Health services (payer/providers) disruption

Providers are facing shortage of personal protective equipment (PPE), nurses, ventilators, and ICU beds across regions.

- As Covid-19 cases continue to grow across regions, hospitals are struggling to meet demand for supplies, including PPE, ICU beds, and ventilators.

Hospitals are facing decline in physician utilization due to a lack of people mobility.

- Non-Covid-19 patients are avoiding hospital consultations.
- The Rx supply chain could also see volume deceleration from a decline in physician utilization.

Covid-19 outbreak to likely impact procedure/surgery volumes; Insurers likely to benefit.

- Providers reporting an increase in procedure cancellations or deferrals.
- The cancellations could benefit insurers, which would otherwise have to pay for expensive orthopedic and cardiac procedures, which typically require inpatient admission.

Health insures to see high medical loss ratio (MLR) due to growing Covid-19 cases.

- We see that senior population and immunocompromised population are the most susceptible. As a result, we would expect any potential meaningful impact on managed care organizations (MCOs) to be the most acute in their Medicare businesses, resulting in a higher MLR, as reported by companies during the 2017-2018 flu season.

Consultants can help partners better understand the supply-and-demand forecasting along the pharmaceutical supply chain

- Consultants can also guide partners on how to leverage advanced technologies, such as AI and automation, to ensure seamless operations.

Hospitals should start increasing capacity, e.g., workforce, beds, and tele-health services, and stockpiling supplies like ventilators and PPEs, while exploring options to diversify supply chains, to meet patient demand.

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Covid-19 patient overflow in clinical facilities and social distancing measures have resulted in delays (or cancellation) in drug trials

- Almost all biopharma companies usually outsource much of their day-to-day operations of clinical trials to CROs. **Disruptions in clinical trials could slow the rate of new drug approvals.**

- Clinical trial sites have temporarily suspended on-site visits for monitors, vendors, and all other non-patient visitors. Several sites have cancelled all non-essential patient visits.

- A Swiss biotech company, Addex Therapeutics, suspended a key Parkinson’s drug trial as many of the patients for this trial are in a high-risk group for Covid-19. Addex was conducting this trial in the US and Europe with a CRO.

- Another biopharma, Provention Bio Inc., has paused enrollment in a late-stage clinical trial for teplizumab in diabetics. The FDA had granted the drug a breakthrough therapy tag in August 2019 for preventing and delaying type 1 diabetes.

**Unanticipated costs due to delay in trials**

- Costs incurred to arrange for participants to receive care at their local sites or virtually, rather than the study site, for required visits.

- Supply chain disruptions

- Individual (trial candidate) disruptions due to illness or closure of facilities

- Additional lab testing (e.g., for Covid-19)

**Analyst Note**

- CROs should expand their service portfolios to adopt virtual and home care service models. Small, tuck-in transactions are expected.

- Professional services firms can help partners assess CROs’ portfolios and identify targets through deal evaluation.

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**Rise in adoption of digital technologies amid Covid-19 outbreak**

Covid-19 has proven to be a catalyst for broader virtual care (telehealth) adoption.

- While several barriers to care have inhibited telehealth in the past, recent actions by CMS, HHS, and other governing bodies have sought to expand its availability nationwide.

- Covid-19 is an ideal use case for telemedicine as it can keep potentially Covid-19-positive patients away from uninfected patients and healthcare providers by allowing remote monitoring.

- The US Congress just passed an $8.3 billion Covid-19 response spending bill, which will allow Medicare to provide telemedicine services to seniors regardless of where they live (previously only reimbursed for patients in rural areas) at an estimated cost of $500 million.

With the increased Covid-19 cases, there is a rise in digital epidemiology tools, chatbot helpers, use of AI applications, EHR guidance tools and rapid response test kits.

- Startups and various technology companies across the globe are developing and launching online apps and tools for diagnostics and testing of the coronavirus.

- Digital technologies are not only playing a key role in physical health, but mental health too. With social distancing being recommended by governments and many people self-isolating, technology is playing an important part in relieving anxiety and supporting mental health.

**Analyst Note**

- Healthcare companies need to identify the products and services they provide that lead to competitive differentiation, and that would benefit the most from digitization.

- Professional services can help partners assess the current portfolio and identify the right opportunities in digitization to integrate/adopt.