CRITICAL PRIORITIES FOR PHARMA AND MEDTECH IN RESPONSE TO COVID-19

By Adam Farber, Ben Aylor, Barry Rosenberg, Torben Danger, and Ulrik Schulze

In their immediate response to the COVID-19 outbreak, pharma and medtech companies have been true to their purpose of serving patients and advancing health. They are focusing on supporting clinicians in diagnosis, treatment, and prevention. Lab testing companies are working around the clock to develop new molecular tests to rapidly and accurately *diagnose* COVID-19. Pharmaceutical companies immediately began clinical trials to test existing anti-viral medicines for relevance in *treating* COVID-19 while they seek new treatments. We already see glimmers of hope as the two largest reference lab companies have successfully made COVID-19 testing available at scale, across the US. Vaccine companies are working diligently to develop new COVID-19 vaccines to *prevent* future infection. One company made headlines by developing a COVID-19 prototype vaccine in just 42 days. (Even under the best-case scenario, an FDA-approved COVID-19 vaccine is likely to be 12 to 18 months away.) The industry has also, of course, taken the necessary steps to protect the health and safety of its own employees.

As the virus takes root in more places, and exacts a fast-rising toll on patients, society, and economies, pharma and medtech companies are facing new questions that go beyond addressing the virus itself. Three of the most pressing are:

- How to sustain the global supply of critical diagnostic kits, drugs, medical supplies, and equipment to treat patients in the face of supply chain disruption?
- How to avoid disruptions to R&D, including ongoing and planned clinical trials, as COVID-19 spreads globally and affects providers?
- How to help patients and customers make it through this disruptive time?

Our BCG colleagues recently published ideas on hbr.org on how to lead your business through the coronavirus crisis. Here

are some specific considerations for the pressures facing pharma and medtech companies that are on the COVID-19 hot seat.

Supply Chain Disruption

COVID-19 puts the global supply chains for both pharma and medtech products under pressure. In the US, up to 80% of active pharmaceutical ingredients (APIs) are sourced globally, including most generics, with China and India playing critical roles. While the most innovative biologics or non-small molecules are made in the US and EU, there are more than 600 US FDA-registered facilities in China, providing more than 1,000 APIs to the US market. A COVID-19 outbreak in India has the potential to further disrupt global pharma supply chains already hampered by the disease in China.

Asia also plays a significant role in medtech supplies manufacturing. Industry executives estimate that Asia produces up to 50% of N95 masks (plus raw materials and fabrics for N95 masks manufactured elsewhere) as well as a large majority of isolation gowns. Fearful consumers are stockpiling these masks for their own use, threatening supplies for physicians and nurses who need them to treat patients (COVID-19 and otherwise). We estimate clinicians caring for COVID-19 patients can easily go through hundreds of masks a month. Several Asian and European countries have placed export controls on "protective apparel," including masks, gowns, gloves, and drapes. Nonwoven polypropylene fabrics used as inputs to make N95 masks are in short supply.

Products used to treat acute viral illness will experience a short-term jump in demand due to COVID-19 admissions. Examples include IV fluids, IV pumps, IV catheters, ventilators, and respiratory disposables. IVD diagnostic tests for flu, respiratory diseases, and COVID-19 will also see increased demand. The impact of these events will vary by company based on product portfolio and other factors, with some seeing the need to mobilize to meet increased demand while others may see demand decline when, for example, non-urgent procedures are postponed because of COVID-19.

While many pharma and medtech supply chains have been able to largely meet demand to date from existing inventory, it is critical that companies activate sophisticated analytics and scenario modelling to fully understand their supply chains and identify the top products facing potential supply issues, with a perspective on the next few months, taking into account potential more-aggressive infection scenarios. This involves:

- Identifying products affected by possible shutdowns at suppliers—and suppliers' suppliers—or logistics interruptions in Asia (especially China)
- Understanding inventory levels in the full supply chain and adjusting to new realities
- Pressure-testing supply chains based on various scenarios for the COVID-19 situation (such as near-term containment, continued regional expansion, and potential "second wave" infections later in 2020)
- Ramping up production at alternate supply sources that are already in place (second-source API or intermediate suppliers, for example)
- Implementing an allocation process for affected products and actively managing the distribution of constrained products
- Initiating the search for additional or alternative suppliers for critical APIs, ingredients, raw materials, and components (recognizing longer timelines are required for technical transfers and regulatory approvals)

In the medium term, as the COVID-19 situation settles and clarifies, companies should take additional steps to bolster their supply chains and operations to withstand the impact of future public health crises.

This can involve multiple steps, including further diversifying (and building further redundancy and resilience into) international supply chains, employing ongoing contingency planning as the new normal, strategically holding inventory to recognize the supply chain risks identified in this global crisis, developing a manufacturing network strategy fit for the future, and strengthening data, analytics, and artificial intelligence capabilities as critical enablers of medium-term resilience.

Sustaining R&D

While pharma and medtech companies rapidly mobilize to address COVID-19, it is also vital to keep R&D in other disease areas on track. We don't know how long it will take, but eventually COVID-19 will be controlled. We do know that other illnesses are not taking a holiday while we focus on COVID-19.

Like any public health emergency, COVID-19 puts additional stresses on pharma and medtech R&D clinical trial programs. First, they need to maintain supplies of drugs and devices for clinical trials. Second, many hospitals and investigators are overwhelmed by COVID-19 patients, and as a consequence have to deprioritize trials. There have been reports of hospitals exceeding capacity in badly affected areas such as China's Wuhan and Italy's Lombardy regions. Third, patients are reluctant to participate in clinical trials because of the perceived risk of being exposed to the new virus. Fourth, pharma companies themselves are concerned that trials may experience adverse events stemming from the COVID-19 outbreak.

Pharma and medtech companies can help address these issues by considering carefully which ongoing clinical trials may be affected by COVID-19 and what can be done to mitigate slowdowns in trial time or success. They should categorize clinical trial operations by business criticality, define clear contingency plans for critical trials, consider where patients are recruited, and put safeguarding measures into place. Potential steps to address these concerns include:

- Identifying the trials that could be affected by possible shutdowns at suppliers or logistics interruptions
- Incorporating COVID-19 risk and impact tracking into trial management plans
- Communicating with investigators to understand what specific issues COVID-19 is creating at their sites (such as local lab testing capacity, patient retention, serious adverse event risks)
- Investigating alternative timing or locations and prioritizing initiation of new investigator sites in countries with lower potential risk
- Putting in place strong patient communication plans
- Establishing an internal regulatory perspective on COVID-19 to guide communications with institutional review boards and investigators
- Working with regulators to understand how to deal with enhanced event risk in currently enrolled patients

Taking Care of Patients

The fundamental mission of health care companies is to advance patient health, and in times of emergency, this concern stands high above all others. Nobody can know what COVID-19 will ultimately mean for global health, affected societies, or the global economy. But pharma and medtech companies are critical parts of mitigating its impact and coming up with a global solution.

In addition to supplying products to aid in COVID-19 diagnosis, treatment, and prevention, pharma and medtech companies may be in a position to help their customers in novel ways. These include special support (such as additional resources) for hospitals in highly affected areas and working with providers to bolster their alternative sites (such as off-hospital clinics, ambulatory surgery centers, offices, and infusion

centers) for medication administration and lower acuity surgery.

Companies can also help in developing solutions for supporting patients in affected areas, such as providing for in-home administration of medicine, transportation to off-site locations, or telemedicine services. They can emphasize the use of digital channels to make sure that customers and patients get what they need. These channels can provide self-serve options for patient service and customer service questions, online ordering, and alternatives to call centers, which could end up short staffed. In some instances, video options can replace face-to-face engagement.

In an environment in which hard information is in short supply, pharma and medtech companies should also think carefully about what they and their sales reps, medical science liaison staff, and others communicate to customers. Messaging about the strength and capacity of their services, including product supply, reimbursement support, and other patient services, will likely be highly reassuring.

In this difficult time, the industry has an opportunity to bring its full resources and best talent to address the pressing challenges that COVID-19 presents to human health.

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