



TOP TAKEAWAYS

Critical Business Considerations for Life Sciences and Medical Device Companies During COVID-19

- 1. FDA enforcement discretion is a flexible, risk-based approach, not a free pass.** Companies operating under FDA's enforcement policies to provide COVID-19 countermeasures should have a strategy to ensure that products comply with the standard applicable requirements if the products will still be in distribution after the public health emergency ends. FDA will prioritize areas for follow-up and review after this crisis; clear documentation and protocols describing deviations from standard FDA procedures or requirements will be important in a post-COVID-19 environment.
- 2. Clinical trials remain an important FDA priority, and COVID-19 presents an opportunity to transform the clinical development model.** The agency has been very flexible in terms of the approaches it is taking to allow trials to continue, including through the use of technology, such as remote patient monitoring, video consent and telemedicine, as well as the use of home health. Such innovations may break down traditional barriers in clinical trials and make them simpler, faster and more patient-friendly. Despite the flexibility, launching new trials and enrolling and monitoring patients will remain a challenge.
- 3. Pivot toward COVID-19 responses and changes to prescription demand will disrupt life sciences supply chains for months to come.** Companies will need to ramp up manufacturing and put new distribution channels in place to meet demand. This will need to be done despite a limited and constrained workforce. There may be delays in foreign and domestic inspections and potentially delays in products coming to market.
- 4. Antitrust compliance remains an important priority, particularly as competitors have begun collaborating to address supply chain issues.** While regulators and companies have been engaged in finding creative solutions to supply chain challenges, the pandemic does not offer carte blanche to engage in anti-competitive activity. Companies should consider proactively engaging with the government where possible with respect to partnerships. When not possible, they should review DOJ and FTC guidance to mitigate enforcement risk down the road.
- 5. Life sciences companies with international footprints can take advantage of government assistance programs from more than one country.** US companies with operations in Europe and European companies with US subsidiaries can take advantage of government assistance programs in the countries in which they operate, depending on corporate structure and asset locations.
- 6. Interdependencies of government assistance programs and tax implications are important to consider.** A wide variety of new government assistance programs have emerged. Life sciences companies are encouraged to examine the interplay of these programs and the optimal approach to meet their needs during the COVID-19 pandemic.
- 7. New strategic purchasers are likely to emerge as life sciences companies face distress.** Between non-US companies that want to enter the US market, companies seeking to expand their existing portfolios and increased interest from private equity funds, one can anticipate seeing lenders and fulcrum creditors entering the life sciences space.
- 8. Connect with restructuring counsel and financial advisors as soon as possible.** Companies facing distress should seek counsel from restructuring attorneys and financial professionals as soon as possible. An increase in bankruptcies should be anticipated. Even if a distressed company does not think it will need to file, it is nevertheless advisable to seek strategic counsel to help proactively evaluate scenarios.
- 9. Liquidity positions should be closely examined.** Cash flow is key, and companies should be implementing systems to evaluate their liquidity position early and often. Failed M&A, failed financing and refinancings are straining life sciences companies. Liquidity strains are an issue, since some companies were running tight even prior to the pandemic.
- 10. Based on data from past recessions, the outlook for life sciences is more positive than that of other industries.** While this pandemic and the resulting economic impact are different from past recessions, data based on three prior recessionary periods indicate that life sciences tend to weather the storm better than other sectors. Recent EY surveys of CEOs and executives project a U-shaped recovery scenario for the industry.

For a deeper dive into these issues, [please listen to our webinar recording](#), co-presented with EY.