

Covid-19 financial implications for pharma

Internal and market disruptions all leaders should be planning for

With the global spread of Covid-19 comes an entirely new set of challenges for pharma. The industry is already experiencing a range of ripple effects—from supply chain disruption, to delayed clinical trials, to the grounding of all field personnel. While much of the impact was felt immediately, several scenarios that could have significant financial consequences have yet to play out.

No one can predict all the ways Covid-19 will influence the industry, but medical and commercial leaders are already asking about the medium-term and long-term implications of the pandemic on their businesses. To help pharma leaders plan for and mitigate the financial consequences of Covid-19, we've compiled a list of the most likely situations pharma will encounter as a result of the pandemic.

Research and Development



Force



Magnitude depends on



Questions to consider

Disruptions in clinical trials for non-Covid-19 products

- Trial sites' ability to mitigate the crisis enough to still participate in clinical trials
- Patients' willingness to seek care in general, which would impact recruitment
- Amount of re-allocation of pharma R&D resources (will depend on organizational culture and governance)

- How easily can manufacturers re-allocate R&D efforts to focus on Covid-19?
- What does the timeline for pipeline planning look like (e.g., 1 year out, 5 years out)?
- Will disruptions mostly be felt for late-stage development projects? Or will there be spillover to early-stage projects as well?

FDA reduces pace of non-Covid-19 drug approvals for 2020 and possibly 2021

- Timeline for a Covid-19 drug/vaccine being approved
- Number of non-Covid-19 products on "backlog" for FDA approval

- What statements has FDA made about efforts to slow or steady the pace of non-Covid-19 approvals?
- Will FDA prioritize approvals for certain therapeutic areas?

Lower regulatory bar and/or changed rules for re-purposing approved drugs for different indications

- Extent to which rules are changed; how broadly rules are applied across drug classes
- Results of early trials for re-purposed drugs

- What statements has the FDA made on this topic?
- Which pre-approved drugs show promise for managing Covid-19?

Research and Development continued...

Force	Magnitude depends on	Questions to consider
<p>Increase in FDA's openness to other sources of data to prove efficacy (e.g., global data, real-world evidence)</p>	<ul style="list-style-type: none"> • Success of non-traditional data sources in proving efficacy for Covid-19 • Whether FDA's openness extends beyond Covid-19 	<ul style="list-style-type: none"> • What are tech giants (AI tools, RWD aggregators) doing to generate or analyze data? • What kinds of studies are getting funded? How are we using RWE to diagnose and monitor? To show efficacy?
<p>Re-purposing approved drugs to treat Covid-19 could limit access for patients who take those drugs for their original indication (e.g., hydroxy-chloroquine for Lupus, RA)</p>	<ul style="list-style-type: none"> • Pharma's ability to increase production of said pre-approved drugs • Impact of indication-based access restrictions 	<ul style="list-style-type: none"> • What does the current supply and demand of chloroquine or other potential treatments look like now? • How sensitive is demand of those treatments to news of their potential promise? • Do patients currently taking these medications have alternative treatment options? • Are any of these potential treatments at high risk of manufacturing or distribution breakdowns or delays?

Manufacturing and Supply Chain

Force	Magnitude depends on	Questions to consider
<p>Manufacturing labor shortages due to Covid-19 infections and/or layoffs</p>	<ul style="list-style-type: none"> • Rate and scope of Covid-19 infections (variable by geography) • Number of layoffs and ability to re-purpose manufacturing staff 	<ul style="list-style-type: none"> • What percent of drugs used in the US are manufactured in the US? • For drugs manufactured outside of the US, how has Covid-19 impacted the workforce to date?
<p>Production declines from potential government-mandated facility shutdowns</p>	<ul style="list-style-type: none"> • State and federal responses to social distancing and quarantine measures, including whether pharma is exempt 	<ul style="list-style-type: none"> • Has there been any evidence of production delays due to facility closures? • What set of levers can the government pull to shut down or re-direct production (and would pharma be exempt)? • What statements has the government made about willingness to shut down/redirect production? • How does the likelihood of facility shutdowns vary by country/state?

Manufacturing and Supply Chain continued...

Force	Magnitude depends on	Questions to consider
Facilities may be (partially) re-purposed to manufacture a new treatment or vaccine	<ul style="list-style-type: none">• Level of shortage of supplies for manufacturing• Number of facilities shut down• Number of facilities that <i>can</i> be repurposed	<ul style="list-style-type: none">• What set of levers can the government pull to direct what manufacturers produce (e.g., Defense Production Act)?• How feasible is it to re-purpose manufacturing sites to produce different drugs? Which sites are best equipped to do so in the short-term?
Changing government import/export restrictions for supplies or APIs (e.g., APIs that only have 60% of their shelf life remaining could be allowed for export)	<ul style="list-style-type: none">• Government decisions about API exporting (especially India)• Inventory churn	<ul style="list-style-type: none">• What proportion of APIs are produced in India, China, etc.?• What statements have those governments made about import/export restrictions? (e.g., India has restricted export of malaria drugs to ensure that they stay within India)
Slowdown in other parts of manufacturing supply chain (e.g., plastics, cardboard for packaging, APIs)	<ul style="list-style-type: none">• Level and duration of global transportation/commerce restrictions (would vary by geography)	<ul style="list-style-type: none">• What are the essential non-drug components of the manufacturing supply chain, and how are those components currently impacted?• What supply chain redundancies are being put in place to mitigate the risk of delays?
Pressure to geographically diversify manufacturing sites to reduce reliance on specific markets	<ul style="list-style-type: none">• Extent to which disruptions in manufacturing negatively impact pharma's' bottom line (in short, is this a storm they could weather again?)	<ul style="list-style-type: none">• What percent of drugs used in the US are manufactured in the US vs China, India or other key markets?• What's the difference in cost (labor, raw goods, etc.) to manufacture in the US vs. abroad?

Distribution and Channels

Force	Magnitude depends on	Questions to consider
Growth in patient preference for mail order pharmacy	<ul style="list-style-type: none">• Duration of social distancing• Extent to which patients feel comfortable picking up prescriptions in person	<ul style="list-style-type: none">• Will these shifts in patient preference last in a post-Covid-19 world?• What changes have we observed in the use of mail order prescriptions to date?
Growth in adoption of telemedicine services	<ul style="list-style-type: none">• Extent to which telemedicine impacts “where” prescribing happens• Legal and regulatory changes (e.g., whether telehealth visits “count” as 340B visits)	<ul style="list-style-type: none">• How has telemedicine changed prescribing already?• Under which circumstances does it matter if a health system vs payer vs PBM vs startup owns the telehealth service?
Pressure on health systems to retain pharmacy business in-house (including retail, specialty, and buy-and-bill)	<ul style="list-style-type: none">• Amount of financial pressure on hospitals as a result of the pandemic• Dynamic among competitor pharmacies and channels (e.g., retail chains, PBM mail order)	<ul style="list-style-type: none">• Which in-house pharmacy services are most profitable for providers?• What levers can health systems pull to steer prescriptions to their in-house pharmacies?

Pricing and Contracting

Force	Magnitude depends on	Questions to consider
Pressure for federal regulation of drug prices, as Medicare & Medicaid funds are depleted	<ul style="list-style-type: none">• Impact of the pandemic on Medicare/Medicaid funds• Timing – severity and duration of pandemic may determine how soon potential legislation makes it to the floor• Political dynamics and public perception of pharma (finding a treatment and pricing it reasonably could create halo effect)• Economic impact of the pandemic (job loss and financial squeeze could increase public pressure to address cost of prescription drugs)	<ul style="list-style-type: none">• What evidence have we seen to date of pharma <i>not</i> making profit-maximizing moves (e.g., shared IP, releasing patents, reducing prices, collaborating)?• What statements has Congress made about timing for drug pricing legislation?• How will the speed at which a treatment or vaccine is developed and the price of said product influence public perception of pharma?
Acceleration toward risk/value-based payment models	<ul style="list-style-type: none">• Level of demand for new payment models among payers/providers• Bandwidth to execute; how staff are re-deployed during the crisis	<ul style="list-style-type: none">• What would a value-based payment for Covid look like?• Even if Covid requires some type of innovative contracting model, will that set precedent for non-Covid models in the future?
Acceleration of deals that incentivize wide distribution (e.g., subscriptions and affordable prices)	<ul style="list-style-type: none">• Number of treatments that work (competition)• How states, payers, and health systems band together to secure affordable access	<ul style="list-style-type: none">• What's the likelihood of having multiple treatments or vaccines for Covid-19? Once we have an approval, will development for other candidates stop?• What kind of pricing models would be feasible for payers and palatable for manufacturers?
Delayed value assessment reviews of non-Covid-19 drugs (ICER already announced they are delaying impact analysis for sickle cell and others)	<ul style="list-style-type: none">• Extent to which other health technology assessment organizations follow suit• Duration of the outbreak and thus extent of potential delays	<ul style="list-style-type: none">• What statements have ICER and FDA and other drug assessment companies made over the last few weeks?• To what extent do payers and other stakeholders use these reviews in decision making (less relevant in the US than in other markets)?• Will pharmas capitalize on this by raising prices, or is that unlikely?

Sales & Commercial Model

Force	Magnitude depends on	Questions to consider
Decline in sales activities as HCPs focus on Covid-19 care or are redeployed to mitigate the crisis	<ul style="list-style-type: none"> • Duration of hospital limitations on non-essential visitors • Extent to which HCPs are redeployed for crisis management (can vary by TA) 	<ul style="list-style-type: none"> • What are providers currently saying about limiting visits from pharma sales reps? • For which drugs will this have the biggest impact? (E.g., new-to-market drugs, branded drugs w/ a generic, drugs with high competition, drugs for chronic disease)
Decline in marketing activities as events are cancelled and customer mindshare is diminished	<ul style="list-style-type: none"> • Where a given drug is in its lifecycle (new to market, patent expiration, etc.) • Duration of event cancellations 	<ul style="list-style-type: none"> • What relevant conferences have already been postponed or cancelled altogether? • What percent of sales are attributed to promotional and/or fundraising activities? How much (if any) of this can be redeployed? • Has there been any observed or expected change in spend on advertising media?

Volumes

Force	Magnitude depends on	Questions to consider
Reduction in new prescriptions written	<ul style="list-style-type: none"> • Level of job loss and economic impact (could impact patients' willingness to seek care) • Regulations regarding prescribing via telehealth platforms 	<ul style="list-style-type: none"> • What is the correlation between household income or unemployment and filling of new prescriptions – was this studied during the economic crash of 2008? • Any observed changes in office visits? • Any observed uptick in scriptwriting via smartphone app/telemedicine platforms?
Reduction in prescription adherence	<ul style="list-style-type: none"> • Financial pressure on patients • Availability of financial assistance through payer, government, or manufacturer • Access to mail order pharmacy, auto-refill programs • Resumed access to HCPs for refills that require a visit • Payer decisions to waive early refill limits (already done by Cigna, Geisinger, and most BCBS plans) • Drug type – route of administration, chronic vs. limited duration, etc. 	<ul style="list-style-type: none"> • What is the correlation financial wellbeing and medication adherence? • What actions have payers already taken to ensure longer-term adherence in the absence of in-person physician visits? • What actions have pharma companies taken to sustain adherence (e.g., BMS and Lilly offering reduced price or free medications) • What is the correlation between mail order pharmacy and medication adherence? Auto refill policies?

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