AT THE COVID-19 FINISH LINE, **HOW DO WE PRICE THE WINNING VACCINE?**

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As of August 21, 2020, there were more than ***165 potential vaccine candidates in development*** for the novel coronavirus. While some are still in preclinical stages, a handful are quickly making their way toward regulatory approval, meaning that pricing is starting to become an urgent reality.

The first safety trials in humans started as early as March, due to various expedited clinical development processes in place around the globe that promised to bring a vaccine to fruition as quickly as 12 to 18 months from the outbreak of the pandemic—an unprecedented time frame that was quick to spark a reaction from critics.

But now, as the reality of a commercialized SARS-CoV-2 vaccine becomes closer every day, countries the world are over are starting to ink deals with various front-running companies in order to ensure supply for their citizens when the time comes.

Dedicating budget and resources to finding and accessing a COVID-19 vaccine means that there will have to be trade-offs in other areas of healthcare, which could trickle down for years to come, so it's important that government bodies and organizations get the best deal possible.

Some companies have already proposed potential vaccine prices, throwing out ballpark figures of anything from around $4 to $72 for a dose, calling into question how much we will actually end up paying for a vaccine.

PROPOSED PRICES

Even with government investment in R&D, vaccine makers are currently fleshing out whether to sell a vaccine at cost price or make a profit. As it stands, there is no clear-cut trend as to whether companies will seek to gain profit from any vaccines that they bring to market. Some companies want only to break even, whereas others (like Moderna) outright stated they are seeking to make a profit.

For example, Moderna has announced that it will not be selling its candidate, mRNA-1273, at cost price, unlike AstraZeneca (AZ) and Johnson & Johnson (J&J). All of them received substantial federal funding in the U.S.

Moderna has estimated that its shot might cost $32-37. Even more, the company is suggesting that the final result could call for two doses per person to provide full immunity from the virus, landing the total cost for vaccination at around $70. AZ, on the other hand, will stand to make no profit during the pandemic from selling its vaccine at cost price, which is substantially lower at around $4 per dose. J&J is currently sitting somewhere in the middle, estimating its vaccine price to be around $21 per dose, again potentially requiring two doses for a full course.

Although it is still in talks and has stressed that the pricing is preliminary, Moderna's candidate has incited concern from critics, such as Illinois Democratic Representative Jan Schakowsky, who noted "it will represent yet another example of why we must require reasonable pricing of COVID-19 vaccines and treatments that have been developed by taxpayers." She also accused Moderna of "already contemplating how to turn its federal funding into sky-high profits."

At the other end of the spectrum, a company that has garnered interest around its exceptionally high pricing is Sinopharm, a Chinese firm that is pricing its candidate at around $72.50 for a shot, or $145 for the whole two-dose course. Notably, Sinopharm has not received any investment in R&D from government bodies.

In addition, it seems to be that lower prices for a vaccine will be only temporary. AZ and J&J have committed to the low prices "during" the pandemic; as for after the event, critics have suggested that if the vaccine requires repeated or booster shots, then the companies are set to make the money back further down the road.

Candidate	Company	Suggested Price Per Dose	U.S. Public Investment	U.S. Public Procurement Deals
mRNA-1273	Moderna	$32-37	Nearly $1 billion pledge from U.S. Government	Extra $1.53 billion for 100 million doses
BNT162b2	BioNTech, Pfizer	$19.50	N/A	$1.95 billion for 100 million doses
AZD1222	AstraZeneca	$4	$1.2 billion pledge from U.S. Government	$1.2 billion for 300 million doses
-	Sinopharm	$72.50	N/A	Candidate
Ad26.COV2.S	Johnson & Johnson/Janssen	$10*	Over $1 billion from BARDA and Department of Defense	$1 billion for 100 million doses
-	Sanofi, GlaxoSmithKline	$21*	$2.1 billion pledge from U.S. Goverment	$2.1 billion for 100 million doses
NVX-CoV2373	Novavax	$16*	$1.6 billion funding from HHS	$1.6 billion for 100 million doses

*Worked out as funding/purchase amounts

ACCESSIBILITY CONCERNS

The higher price brings concern about accessibility. The Vaccine Alliance (GAVI) previously noted that at least 60% of the world's population will need to be vaccinated to achieve herd immunity and start to eradicate COVID-19 completely; but if a vaccine isn't affordable to all, we have less of a chance of achieving this ultimate goal.

GAVI is also seeking to negotiate tiered pricing for richer and poorer countries via the COVAX Facility, which constitutes 75 countries that have submitted expressions of interest to help guarantee rapid, fair and equitable access to vaccines.

These countries will support lower-income countries by financing vaccines from their own national budgets and through voluntary donations to GAVI's COVAX Advance Market Commitment, a funding instrument aimed at incentivizing manufacturers to produce enough vaccines and ensure access for developing countries.

PRICING MODELS

In June, the Institute for Clinical and Economic Review (ICER) released a white paper detailing six alternative approaches for pricing novel vaccines and therapies in the U.S., in which it specifically analyzes the potential advantages and disadvantages of the approaches that policymakers from around the world "must now confront":

- **STATUS QUO:** Unrestricted pricing—private companies develop vaccines and treatments, are rewarded with patent rights and are allowed to decide how much to charge for the resulting products within a monopoly pricing paradigm.
- **COST-RECOVERY PRICING:** Private companies develop vaccines and treatments and are rewarded with patent rights, but government and/or private insurers use an analysis of the cost of development and production to set a ceiling price.

- **VALUE-BASED PRICING:** Private companies develop vaccines and treatments and are rewarded with patent rights, but government and/or private insurers use some form of cost-benefit analysis to set a ceiling price based on the degree of added benefit for patients and society.
- **MONETARY PRIZES:** The government establishes a specific prize amount to incentivize discovery, with the first private company to discover a successful vaccine being awarded the prize. The government keeps the intellectual property and contracts separately with entities to manufacture and distribute the vaccine at cost.
- **COMPULSORY LICENSING:** In exchange for royalties paid to the innovator, the government permits others to make, use, sell or import patented pharmaceuticals without the patent-holder's permission. This approach includes the possibility of exercising "march-in" rights to mandate licensing of the product directly to the federal government.
- **ADVANCED MARKET COMMITMENTS AND SUBSCRIPTION MODELS:** Advanced market commitments are designed to incentivize the development of novel treatments and vaccines by subsidizing the research and development costs through a commitment by the funder (or a pool of funders) to a future purchase price if the development is successful. Subscription models can work somewhat similarly, with funders and innovators agreeing on a price for a treatment in a way that provides a guaranteed minimum return on investment and a cap on total costs no matter how many patients need treatment.

Speaking at the time of the paper's release, Steven D. Pearson, president of ICER, noted, "One critical issue will be how new treatments will be priced to ensure that this goal can be met. In the exceptional circumstances of the coronavirus pandemic, the early decisions made regarding pricing policy will guide further decisions in the coming months that will have enormous consequences for the United States and the rest of the world."

However, critics have since noted that the approaches may be "fairly academic" and are "exceedingly difficult" to implement, explaining how it is hard to know an exact formula because "we're dealing with an exceptional circumstance."

Another glimpse into a potential pricing model was provided when ICER also released its updated analysis on the pricing of Gilead's antiviral remdesivir (now marketed as Veklury). Despite being a treatment as opposed to a vaccine, at the time (June 2020) the drug was hailed as a basis for the pricing of both future COVID-19 treatments and vaccines.

ICER adopted two pricing models for remdesivir: the cost recovery model and the traditional cost-effectiveness model, in which the incremental health benefits and costs within the health system are examined. The Institute published an initial analysis of remdesivir but decided to follow suit with an updated analysis due to more available data on the manner.

For the cost recovery model, ICER's updated benchmark price for a full course of remdesivir was $10 to $600, considering only the marginal cost of producing the antiviral; and $1,010 to $1,600 if considering the drugmaker's forecasted 2020 clinical development expenses.

COLLABORATION

Despite the initial companies' reasonable pricing suggestions quelling major concerns so far, there are many unprecedented issues to overcome when globalizing a vaccine in such a short time frame, and countries need to work internationally now more than ever—particularly when it comes to the purchasing of candidates, as demonstrated by Europe's efforts to secure access for its member states.

The European Commission recently wrapped up exploratory talks with Moderna regarding purchasing the company's potential vaccine candidate,

anticipating it will have a contractual framework in place for the initial purchase of 80 million doses on behalf of EU member states, with an option to purchase a further 80 million doses.

The Commission has already spoken with Sanofi-GlaxoSmithKline, J&J and CureVac and signed an advance purchase agreement with AZ, all in the name of gaining access to whichever vaccine proves to be the most successful.

The cross-border collaboration involved in these deals is a promising glimpse into the future for the pharma industry, and EU member states that have previously signed an agreement with the European Commission have also agreed to refrain from negotiating individually with producers and from competing with each other, again demonstrating the benefit of working cooperatively.

HERE TO HELP

EVERSANA uniquely has the people, methods and tools to assist businesses in navigating global pricing policy, even in such unsure times. This expertise is built on our combined decades of experience solving problems in and building tools for global pricing intelligence, global visibility and product launch expertise, which puts us in a trusted position to advise clients on how to handle these changes.

Pricentric Insights delivers accurate, comprehensive insights on major policy and regulatory changes, as well as HTA decisions and drug approvals, in 100+ markets around the world. Our team of researchers checks a database of over 700 reliable sources, including everything from government databases to local newspapers, to provide readers with in-depth updates on the ever-changing pricing and reimbursement landscape. We also provide conference coverage and utilize our team of consultants to detail how major policy changes can impact market access and the global pricing landscape.

As the pandemic continues to develop, Pricentric One is tracking the updates closely to help provide you with in-depth, up-to-date information. We're updating the newsfeed with prices in real time, helping you make the most accurate and informed decisions.

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