LAUNCH & SCALE SPEEDOMETER

Issue Brief: Deciphering the Manufacturing Landscape for Covid-19 Vaccines

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Duke | GLOBAL HEALTH Innovation Center

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In the race for global equity of Covid-19 vaccines, there are several critical interconnected pillars, including vaccine research and development; purchases; manufacturing; distribution; and vaccinations. In late 2020 and early 2021, purchases were the primary marker of who would get vaccines and who would be left behind. Whether and when, and the terms under which countries are able to negotiate purchase agreements, and how overall purchases are prioritized across the world, remain important. We have been aggregating and analyzing global vaccine purchase data weekly since November 2020.

Now, several vaccine candidates have shown promising efficacy and safety in clinical trials and have undergone regulatory reviews at national, regional, and global levels. Over 400 million doses have been administered in over 130 countries so far, but manufacturing and supply have become critical constraints for global access and equity. Countries are looking to production estimates and delivery schedules to understand what they will have and when. The manufacturing landscape is highly dynamic, both expanding and contracting daily. New partnerships, including among rivals, have exponentially increased capacity, while production optimization and scaling challenges, as well as limited availability of certain raw materials, have caused reductions in projections.

Demand for Covid-19 vaccines will outstrip supply over the coming months. In this environment, there is no cushion and even small setbacks could cause supply shocks.

Despite the importance of manufacturing to Covid-19 vaccine availability and equity, the landscape itself is remarkably opaque. Publicly available information on production, including partners, locations, roles, and projections, is scarce and fragmented, making it difficult for policy- and decision-makers to fully understand the various supply chains involved, take stock of the risks, and take urgent action where it is most needed in this global effort. For example, what are the root causes of current manufacturing constraints, and what might be the implications of changes in IP/tech transfer frameworks like the WTO TRIPS agreement? What might be the implications for sudden changes in manufacturing, availability, or use of specific vaccines (e.g., several countries recently paused use of the AZ/Oxford vaccine)? Where are we seeing centralized versus distributed approaches to manufacturing, and what are the implications?

To help address this challenge, and building from our recent effort to track vaccine purchases globally, we have now developed a data structure to track and publicly report manufacturing by vaccine and location, with linkages to our purchase data. Over the past several weeks we have attempted to obtain and analyze all publicly available information about vaccine manufacturing and aggregate this data within our new data structure. We are pleased to make this data, and associated insights and visualizations, publicly available today at https://launchandscalefaster.org/covid-19/vaccinemanufacturing and we will provide weekly updates going forward.

It is important to recognize that this data is not comprehensive, as there are still many unknowns, but we are aggregating the information that is available to enable better insights

and decisions globally. We hope that by highlighting the data gaps, we will encourage others to join this effort and help to fill in missing data points and bring more clarity to a murky system.

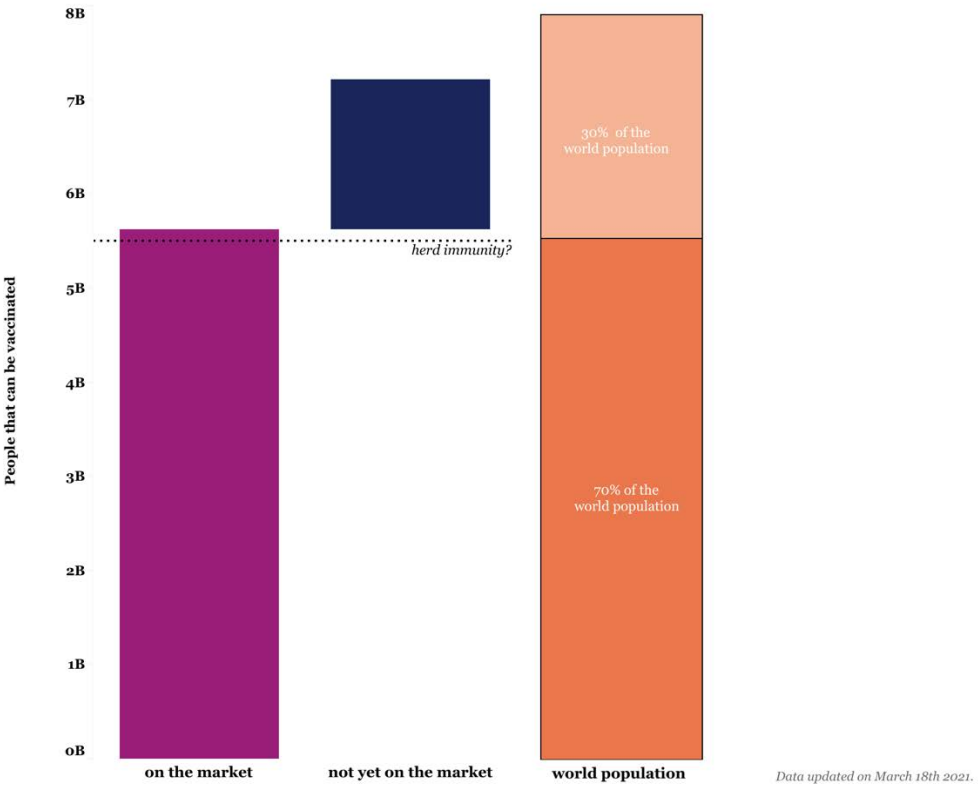
Key takeaways from the first release of manufacturing data

1. Projected doses for calendar year 2021 could support initial needs globally if distributed equitably

Our analysis of 2021 projections from Covid-19 vaccine makers indicates that **more than 12 billion doses could be produced this year**. This is aligned with other recent estimates that range from 9.5 to 13.5 billion doses.

Assuming the market is primarily 2-dose vaccines (Janssen and CanSino are the only 1-dose vaccines currently on the market), about 11 billion doses are needed to vaccinate 70 percent of the world's population. This is frequently seen as the threshold to approach herd immunity, the level of vaccination coverage that limits spread and protects those who are unable to be vaccinated from infection.

Chart 1: Projected Global Supply by World Population



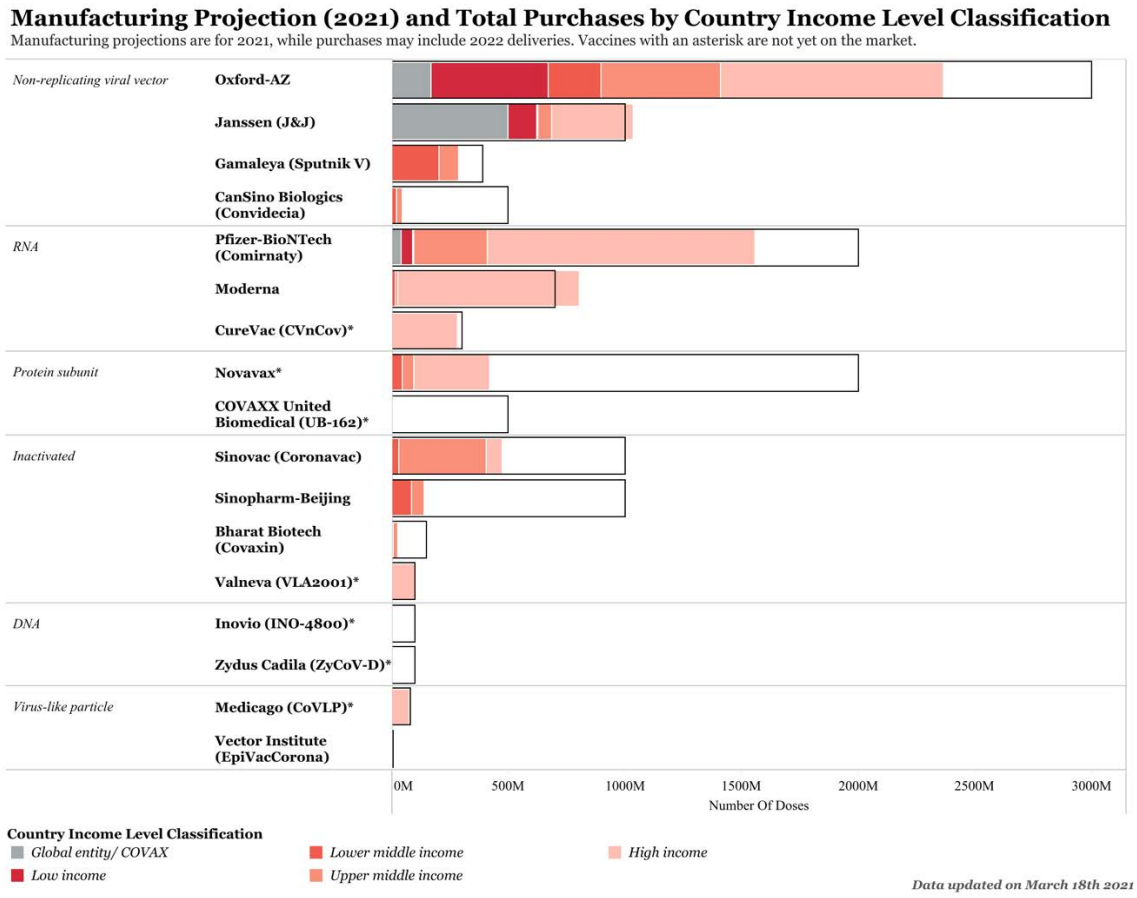
If manufacturers are able to reach their goal of 12 billion doses this year and if those doses were purchased and distributed equitably across the world's population, we could meet much of the world's needs in 2021. (It is worth noting that those are both big ifs.)

Global needs can change, however. For example, the emergence and spread of new variants may mean that we need a new generation of vaccines before the end of 2021. We also do not yet know how long immunity from vaccines will last and we may need regular booster shots to maintain immunity and to target new variants. No vaccines are yet approved for use in children under 16 years of age, but several are being tested in children now. The approval of one or more vaccines for children could shift the demand and supply landscape again. Some countries may also choose to purchase and maintain surplus vaccine doses beyond their immediate needs in order to manage future risks, diminishing the immediate supply for other countries.

2. Production capacity for 2021 varies widely among vaccines and vaccine platforms

To meet the global total of more than 12 billion doses projected in 2021, production will need to increase on a scale we have not seen before. The capacity expansion is not evenly spread across vaccine makers, though. The 2021 supply will be dominated by Oxford-AstraZeneca, Pfizer-BioNTech, and Novavax (which is still awaiting regulatory review).

Chart 2: 2021 Manufacturing Projections and Confirmed Purchases



While Oxford-AstraZeneca will likely remain a front runner, we expect to see projections increase for Janssen (J&J) and Sputnik V, also non-replicating viral vector vaccines, over the next few months.

Projections for vaccines using DNA and virus-like particle platforms are lower than other vaccine platforms but this is at least partly explained by their earlier stage in development. Only one of these (Vector Institute's EpiVacCorona) is on the market (and only in Russia). Production and use of EpiVacCorona is not expected to begin in Russia until later in March; manufacturing projections will likely increase for this and other early-stage vaccines if they receive regulatory approvals.

Both **China** and **Russia** are depending on domestic vaccines for their national supply but that is not well reflected in this data, given the lack of publicly available information on purchases or doses allocated to domestic supply in either country. If China's potential domestic allocation is factored in, Sinopharm-Beijing, Sinovac, and CanSino may have limited additional manufacturing capacity for exports in 2021. Domestic allocation of Sputnik V in Russia likely puts its market commitments far beyond current manufacturing capacity for 2021.

In addition to what is presented in the chart above, **COVAX** is depending on nearly 1.1 billion doses of Novavax's vaccine and another 550 million doses of Oxford-AstraZeneca's vaccine. As these doses are either currently under negotiation or optioned, they are not reflected here as confirmed purchases. If the Novavax purchase is finalized and Novavax and Oxford-AstraZeneca options are exercised, this will take the majority of remaining 2021 capacity for both vaccines.

3. Manufacturing approaches and partnerships correlate with capabilities and distribution priorities

Vaccine makers can be loosely categorized into two manufacturing approaches, the global, distributed approach versus the centralized, in-house approach. Most fall somewhere in the middle but we see clusters at both ends of the spectrum.

Oxford-AstraZeneca typifies the **distributed approach**, with many technology transfer deals and manufacturing distributed across several regions globally. Novavax and Sputnik V also fit within this cluster.

Chart 3: Manufacturing Countries (and partners) and Purchasing Countries for Oxford-AstraZeneca

On the other side of the spectrum are Pfizer-BioNTech, Moderna, Janssen (J&J), and Sinopharm-Beijing with a **centralized approach**. These vaccine makers are keeping manufacturing largely in-house and working with one or two big partners. Their manufacturing tends to be concentrated in one or two regions globally.

This clustering may be tied to the varied capabilities and assets of each vaccine maker rather than being an intentional strategy. Without significant in-house vaccine manufacturing capacity, for example, AstraZeneca is reliant on global partnerships to reach its supply goals. Conversely, Pfizer and BioNTech had large capacity in addition to well-established manufacturing partnerships already in their key markets. In addition, there are fewer manufacturing partners ready to produce mRNA vaccines, which means Pfizer-BioNTech and Moderna had a more limited global pool than others.

Global purchase patterns tend to reflect the manufacturing approach. Those taking a distributed approach generally have prioritized this in their sales as well and have a larger reach in terms of numbers of countries and regions purchasing their vaccine. The vaccine makers taking a centralized approach are often prioritizing their manufacturing locations for sales and 2021 deliveries.

One notable exception is Pfizer-BioNTech, which was the first vaccine to get approval from a stringent regulatory authority (UK) and the first to receive WHO emergency use listing (EUL). This first-out-of-the-gate status, combined with high efficacy data, has contributed to distributed global purchases.

4. Bulk of COVAX supply likely to come from AstraZeneca and Novavax in 2021

The COVAX supply will depend largely on AstraZeneca and Novavax, both of which have large manufacturing capacity in the global South. The manufacturing data suggest that the majority of mRNA vaccines will stay in wealthy countries and will not be a significant source of COVAX supply in 2021. This may shift in 2022, when orders for the US and Europe are fulfilled and Pfizer-BioNTech and Moderna's capacity can shift to other countries.

COVAX can only ship doses that have received EUL from the WHO. This means that vaccines from China as well as Sputnik V from Russia would need to achieve that designation before they could form part of the COVAX supply.

Call to Action: Increase Data Transparency and Availability

Vaccine supply is driving policies and decisions in public health, vaccine purchases, and regional investments. Discussion of issues such as the risk of variants by region, the role of local manufacturing, and the relative impact of intellectual property waivers need to be informed by up-to-date, transparent data.

We encourage everyone to help us build this data set: fill in the gaps, correct mistakes. Let us know what we have missed, data sources we could use, and how this data might be useful.

The manufacturing data and visualizations can be found here, while the purchase data is here. Both data sets are updated weekly.