

Manufacturing and moving towards a more equitable and distributed system



Vaccine manufacturing must be set up before the vaccine itself is fully tested or indeed approved for use. The establishment of manufacturing facilities is one of the most significant costs in the vaccine development process (>\$500 million) and takes up to 5 years. The fact that these investments must be made upfront, and at-risk during Phase 3 trials is a key barrier for many vaccines.

To enable the vaccines of the future to be developed and equitably distributed, we need to make progress towards addressing the very high costs and technical feasibility of manufacturing biological products.

Why now?

At present global capacity and expertise for the manufacture of vaccines as highly complex biological products, is concentrated in a few countries and regions. Due to the nature of vaccine production processes, a factory set up to produce one vaccine cannot be easily adapted to produce another. Moreover, setting up a new production site for a vaccine with a new manufacturer can require an extensive process of 'technology transfer' involving partnership agreements and many months of staff training.

There has been huge interest and debate in the manufacturing of vaccines due to Covid-19. The pandemic has seen the tripling of vaccine production globally from 5.5 to 16.5 billion.^{1,2} However, production is not distributed globally and a combination of export controls and buying up of vaccine supply has led overall to highly inequitable distribution of Covid-19 vaccines. Many believe more distributed manufacturing capacity will be key for the future. There has also been debate on intellectual property

regarding vaccines, and whether by suspending IP rights, increased production of Covid-19 vaccines could occur around the world.

What are the potential solutions?

A number of solution areas are highlighted from our research:

- **Innovation** – Technical innovation in the manufacturing process could upend manufacturing challenges, such as increasing interchangeability and shortening lead times. For example, mRNA is one very promising example. Progress could cut an estimated 3 years and \$275 million from vaccine development.
- **Partnerships** – To enable technology transfers and increase regional manufacturing of vaccines, there needs to be a greater number of suitable companies and sites able to undertake the work. This is linked to a broader problem of available partners to commercialise vaccines after initial development by academic institutions or biotech companies.
- **Financial sustainability** – For manufacturing facilities to be maintained, they need to be financially sustainable, i.e. they need to be developing viable products that are actually bought.

For the short to medium-term if we want better global distribution and to enable innovation in vaccine manufacturing, investments will be needed at a global and government level. There are a range of initiatives being advanced that could provide this, but it is vital that they are sustainable beyond the current pandemic.

¹ WHO. (2020). Global Vaccine Market Report. https://www.who.int/immunization/programmes_systems/procurement/mi4a/platform/module2/2020_Global_Vaccine_Market_Report.pdf?ua=1

² Airfinity. (2021, September 5). Airfinity – Predictive science intelligence [Press release]. <https://www.airfinity.com/insights/more-than-a-billion-available-stock-of-western-covid-19-vaccines-by-the-end>