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## NEWS ANALYSIS

### Covid-19: Pre-purchasing vaccine—sensible or selfish?

High income countries such as the UK and the US have pre-ordered vast amounts of candidate covid-19 vaccines ahead of their regulatory approval. Are such policies nationalistic—or good practice?

**Ingrid Torjesen** investigates

Ingrid Torjesen

#### Why are countries ordering covid-19 vaccines before they are licensed?

Vaccine development is an expensive and risky process that follows a sequential and stepwise course, where companies typically wait for the data from the previous phase before moving on to the next.

Pre-ordering is not just about ensuring access to the first batches of vaccine but about speeding up the process, says Alex Harris, head of global policy at the Wellcome Trust. He explains, “In this instance, the essential benefit of having already made upfront investment—in, for example, manufacturing the vaccine at risk [making it with no certainty that it will work] and building a stockpile significantly—outweighs the cost of that vaccine failing.”

Harris believes that governments are striking deals early because, without the upfront investment from rich countries, they recognise that vaccine manufacturers would not be making any vaccine at risk: they would wait until they had all of the safety and efficacy data and then get regulatory approval. “Then there would be an almighty bunfight for that very limited supply in six to nine months, and the company would say it’s going to take us some time to ramp up our manufacturing,” he says.

#### What has the UK ordered?

The UK government has agreed deals for 340 million doses of vaccine from six companies:

- Adenovirus vaccines—100 million doses being developed by Oxford University through AstraZeneca (with as many as 30 million doses available by September) and 30 million doses from Janssen
- mRNA vaccines—30 million doses from BioNTech/Pfizer
- Protein adjuvant vaccine—60 million doses from GSK/Sanofi Pasteur and 60 million doses from Novavax
- Whole inactivated virus vaccine—60 million doses from Valneva, with an option to acquire a further 40 million doses if the vaccine proves safe and effective.

The UK has also ordered a million doses of AstraZeneca’s treatment containing covid-19 neutralising antibodies to protect people who cannot receive vaccines, such as those with cancer and immunocompromised patients.

There are many reports of other deals between the US, Brazil, and the EU, to name a few. The US government has a deal to spend \$1.95bn (£1.49bn; €1.65bn) on 100 million doses of BioNTech/Pfizer’s candidate vaccine, the *Financial Times* has reported.

#### Why has the UK ordered more doses than it needs?

There is no certainty that any particular vaccine will succeed or when it will be available, so, rather than backing a single horse, countries are spreading their bets. A government spokesperson told *The BMJ* that it was investing in a diverse portfolio to maximise the chances of finding a successful and effective vaccine as quickly as possible.

The UK is also likely to need more than one vaccine because efficacy profiles and other characteristics may vary in different population segments, says Harris.

Sheuli Porkess, the Association of the British Pharmaceutical Industry’s (ABPI) executive director, research, medical and innovation, says that the UK’s approach “should not be interpreted as ‘vaccine nationalism.’” As well as securing their own supplies, rich nations and vaccine companies are supporting international collaborations to ensure that low and middle income countries have fair and equitable access.

#### How much have these deals cost?

The UK government said that the deals were commercially sensitive and would not say what it had paid up front or whether it would get any money back if the vaccines did not work.

## What happens to the surplus doses?

The government said that the UK was committed to supporting equitable and affordable access to new covid-19 vaccines and treatments around the world. Harris comments, “The UK has publicly acknowledged that if more than one or two of the vaccines that they’ve invested in succeeds, they may be left with oversupply. I know that they have every intention of contributing that supply into an initiative [to supply vaccine to poorer countries].”

## Has the UK pre-ordered a vaccine or drug before its approval before?

No, this is a first.

## How do vaccine manufacturers decide who to sell to?

Having to decide which country gets a vaccine first, and how much, is not a job vaccine companies relish, says Harris. “The vast majority of vaccine manufacturers have committed to supply their vaccine at cost and that is certainly not normal, and they have been quite clear in that they would prefer governments to get together and solve the allocation problem for them,” he told *The BMJ*.

The ABPI’s Porkess says, “The reality is that, once a vaccine is discovered, demand will outstrip initial supply. We want to make sure that as many doses of a safe and effective vaccine are made available, as fast as possible, to the people that need them most.

“But doing so is a collective responsibility, which is why we need highly coordinated and collaborative action by the public and private sectors, and why, as manufacturers scale up production, we are also working with governments around the world to have those discussions.

“It is imperative we now work together and leaders align on allocation principles to ensure equitable access for covid-19 vaccines at global and national levels.”

## How will low and middle income nations get early access to vaccines?

Gavi, the Vaccine Alliance, along with the Coalition for Epidemic Preparedness Innovation and the World Health Organization, is leading the COVAX Facility “to ensure we do not re-make the mistakes of the past by allowing a situation to develop whereby only a few countries are able to access global supplies of vaccines, leaving the vast majority of countries out of luck,” says a spokesperson for Gavi. “We saw this happen with H1N1, but covid-19 has had a far more devastating impact already.”

## How does the COVAX Facility work?

Gavi would like all countries with the means of purchasing their own doses of vaccine to do so through the COVAX Facility. Part of that payment will cover vaccines for their own country, and part will be an investment in vaccines for poorer countries. The funding would allow Gavi to invest in research and development and the manufacture of a range of vaccine candidates and to ensure equitable access to vaccines for the people most at risk everywhere in the world, regardless of their ability to pay. The Gavi COVAX Advance Market Commitment (AMC)—modelled on the successful pneumococcal AMC and funded primarily through official development assistance—will support participation of 92 lower income economies.

## Has the UK signed up to the COVAX Facility?

The UK is among 81 countries that have expressed interest in joining the COVAX Facility. The UK government has also committed £250m (€278m; \$328m) to the Coalition for Epidemic Preparedness Innovations—the biggest investment of any country—to support equitable and affordable access to new coronavirus vaccines and treatments around the world.

## What is equitable access?

WHO has put together a fair allocations framework, which estimates the proportions of the population in countries of different income levels that are at the greatest risk and should receive the vaccine first.<sup>1</sup> The framework prioritises healthcare system workers for vaccination, followed by people over 65 and those with comorbidities.

“That allocations framework is not enforceable—it is a tool,” says Harris. Many world leaders have said that “we cannot have a world of haves and have nots,” but they have yet to commit to how they will make that happen. He adds, “Some consensus at the highest political levels is really what is required, and some public statements,” as well as countries committing to covering only their priority populations during the early stages.

Interim advice from the Joint Committee on Vaccination and Immunisation identified the likely priority groups for vaccination in the UK as frontline health and social care workers, followed by people at increased risk of serious disease and death from covid-19 infection because of age or other risk factors.<sup>2</sup> As well as comorbid conditions—including chronic heart disease, chronic kidney disease, chronic pulmonary disease, malignancy, obesity, and dementia—other factors seem to increase risk, including deprivation and ethnicity, urban location, and being over 50.

As more evidence emerges on groups at risk, the composition and priority of groups for vaccination will be reviewed and refined, says the joint committee.

## Which countries have committed to equitable access?

Like many countries, the UK government has committed to supporting equitable and affordable access, but it has not outlined how it will achieve this.

EU countries have gone one step further. The EU vaccine strategy is essentially a buyers' club that strikes deals on the same terms for all member states signed up, and these members have also committed to initially purchasing only for their priority populations, says Harris.

The US, which has formally left WHO, seems to be pursuing an "America first" policy. Reuters has reported that the US health secretary, Alex Azar, said on 10 August, "Our first priority of course is to develop and produce enough quantity of safe and effective [Food and Drug Administration] approved vaccines and therapeutics for use in the United States. But we anticipate having capacity that, once those needs are satisfied, those products would be available in the world community according to fair and equitable distributions that we would consult in the international community on."<sup>3</sup>

### Why is equitable access so important?

Harris says, "You could make the case altruistically that rich countries shouldn't just be securing their own deals, but it goes beyond that to enlightened self-interest."

If a country such as the UK, the US, or Germany secured enough vaccine doses to treat its whole population but this meant that other countries could not get any vaccine, he explains, "all you're doing is protecting your citizenship: you are not actually stabilising and returning your economy to growth, because you can't trade, you have to close your borders."

A Gavi spokesperson concludes, "The economic burden of this approach—aside from the human cost—would be catastrophic."

**Correction:** In "What has the UK ordered?" we amended "350 million" to "340 million" on 17 August 2020.

- 1 World Health Organization. WHO member states briefing: a global framework to ensure equitable and fair allocation of covid-19 products and potential implications for covid-19 vaccines. 18 Jun 2020. [https://apps.who.int/gb/COVID-19/pdf\\_files/18\\_06/Global%20Allocation%20Framework.pdf](https://apps.who.int/gb/COVID-19/pdf_files/18_06/Global%20Allocation%20Framework.pdf).
- 2 Department of Health and Social Care. Joint Committee on Vaccination and Immunisation: interim advice on priority groups for COVID-19 vaccination. 18 Jun 2020. <https://www.gov.uk/government/publications/priority-groups-for-coronavirus-covid-19-vaccination-advice-from-the-jcvi/interim-advice-on-priority-groups-for-covid-19-vaccination>.
- 3 US's Azar says any US vaccine would be shared once US needs met. *Reuters* 2020 Aug 10. <https://www.reuters.com/article/us-taiwan-usa-health-coronavirus/u-s-s-azar-says-any-u-s-vaccine-would-be-shared-once-u-s-needs-met-idUSKCN2560TV?il=0>.

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