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VACCINES

Covid-19—How Europe's vaccine donations went tragically wrong

Covid vaccine equity remains out of reach, as wealthy nations drag their feet on donations, and vaccine stocks pass their use-by dates, write **Lucien Hordijk** and **Priti Patnaik**

Lucien Hordijk, Priti Patnaik

On 21 December 2021, a truck piled with brown cardboard boxes drove to the Goja rubbish dump in Abuja, Nigeria. Inside the boxes were a million doses of AstraZeneca's covid-19 vaccine, which were tipped onto the heap, among dirty plastic bags and papers.

Two months earlier, Nigeria had agreed to receive 2.6 million doses of the vaccine from the Covax facility, an initiative set up to distribute covid-19 vaccines equitably worldwide. The vaccines, in large part coming from Europe, had been close to expiry. "Some of these vaccines came in with a shelf life of about four weeks," said Faisal Shaibu, a Nigerian government official tasked with organising vaccination of the country's 200 million population against covid-19. Following quality inspections and regional allocations, Nigeria administered 1.53 million doses. But the rest were thrown away.

Nigeria, Rwanda, Kenya, and Indonesia have destroyed vaccines received from Europe and North America because they arrived close to expiry.¹

According to the pharmaceuticals industry, supply of vaccines is no longer a problem. "With almost a billion vaccines now being produced every month, countries' lack of capacity to vaccinate is now the main barrier to stopping covid-19," said Thomas Cueni, director general of the International Federation of Pharmaceutical Manufacturers & Associations.² "It's scarcity of vaccination, which is due to the lack of country readiness, absorption capacity, and the lack of resources needed to get the vaccines into arms."

But others say the industry, and donor countries, are shying their responsibilities.

"I'm sceptical about the claim that this is now solely a demand [side] problem," says Katerini Storeng, associate professor at the Centre for Development and the Environment at the University of Oslo. "I wonder how the absorption capacity of the recipient countries would have looked if donations started earlier and arrived more evenly."

When vaccines were first available, countries in Europe and North America over ordered. At the end of 2021, prompted by the fast depleting shelf lives of vaccine stocks, the same countries began to donate doses to countries in the developing world, creating sudden spikes in supply. These donations came too late.

EU promise

The European Union has pledged to donate 700 million doses before mid 2022. According to Airfinity, a provider of health intelligence, Europe has so far delivered 379 million doses, and the United States 535 million.

In January 2022, Airfinity calculated that 240 million vaccine doses stockpiled in wealthy countries could expire by mid March. In the same month, Unicef estimated that 100 million doses had already expired globally. Both organisations were unable to track actual expiry and wastage, according to spokespersons, because the data get murkier as the pandemic persists. Increasingly donations are delivered directly from the manufacturer to the donee country, says Sarah Harper of Airfinity, which makes it difficult to determine what the remaining shelf life is.

"The statistics about wasted doses get blurry, although this data shouldn't be difficult to get hold of," says Antoine de Bengy Puyvallée, a researcher at the Centre for Development and the Environment at the University of Oslo. "But the contracts of the European Union member states [with vaccine suppliers] have been published and they don't lie. They contain no specific clauses for equitable access. The priority for countries was to secure [supplies for] the domestic populations. The international aspect was neglected."

In 2021, the EU ordered two billion doses from six manufacturers. Some 916 million doses were delivered and 702 million administered in the EU. Today, orders total 4.2 billion doses from eight companies, enough to vaccinate the population of the EU nine times over.

Covax was pushed to the back of the queue with manufacturers, so donations from rich countries became the mainstay for the global south until the second quarter of 2022. A recent analysis from the University of Oslo estimates that donated doses account for roughly 60% of the doses Covax delivered in 2021.³

However, donations could not compensate entirely for the lack of direct procurement deals, and Covax delivered less than half of the two billion doses originally promised. "Although dose sharing helped Covax's vaccine delivery, its impact was undermined by donors' and industry's pursuit of national security, and diplomatic and commercial interests, which

Covax largely accommodated,” the Oslo researchers concluded.

By late April 2022, EU member states had vaccinated 72.6% of their populations with two doses and roughly half with a booster dose as well, according to data from the European Centre for Disease Prevention and Control (ECDC). The *Financial Times* estimated that the number of boosters administered in high income countries is nearly double that in low and middle income countries.⁴

Shifting doses—and risk

Giving away surplus vaccines is not as easy as it sounds. The European Commission discovered it could not donate some vaccines without the permission of their manufacturers, according to a leaked letter from October 2021 seen by *The BMJ*, although it remains unclear which companies were referred to.

“Manufacturers seemed to take advantage of the member states’ contractual obligation to obtain their prior written consent in order to hamper vaccine transfers they deem potentially prejudicial to their commercial interests,” wrote a German diplomat to Sandra Gallina, Brussels’ chief negotiator. The official claimed companies “dictate minimum sales prices,” impose “exaggerated compensation schemes” on recipient countries, and “prohibit distribution” to international organisations.

Facing criticism, in November 2021 vaccine manufacturer Moderna announced it would permit the EU to donate 70 million doses of its mRNA vaccine to Covax.⁵ Manufacturer Pfizer was silent on the issue.

The pharmaceuticals companies have demanded that countries using their vaccines indemnify them against any liability claims resulting from rare adverse events associated with vaccination. When European Union member states sought to donate their doses, they passed the risk to the receiving country. A tripartite donation agreement between Italy, Libya, and AstraZeneca seen by *The BMJ* states that recipient countries (in this case Libya) “under all circumstances indemnify and hold member states harmless from all claims and losses” that could occur after use of the vaccines, whether the claim or injury “originates from the distribution, administration, and use, clinical testing or investigation, manufacture, labelling, formulation, packaging, donation, dispensing, prescribing or licensing” of the product.

As a result, NGOs and organisations seeking to administer vaccines in conflict zones or hard-to-reach areas also have to assume the risk. In Syria, Afghanistan, and Congo, Médecins Sans Frontières sought the help of the United Nations to acquire vaccine doses, but had to agree to carry the legal risk if any individual vaccinated were to experience one of the rare but established side effects. “In order to protect our doctors and nurses in hospitals, we chose to carry this risk,” said Judith Sargenti, deputy director of MSF in the Netherlands. “In the end, the [vaccine] companies were able to shift their legal responsibility for their own products to an NGO.”

Shelf life

Also complicating donations is the short shelf life of some vaccines, in particular AstraZeneca’s. In December 2021, Tedros Adhanom Ghebreyesus, director general of the World Health Organization (WHO), lamented, “Too often, countries receive unexpected deliveries of doses close to expiry, with far too little transparency of when doses will arrive (...) More than two thirds of donations are of vaccines with less than three months’ shelf life remaining.”

Early in the pandemic, the Covax facility bet heavily on the AstraZeneca vaccine to supply the global south. The vaccine was relatively inexpensive and could be stored easily, but it also had a short shelf life of six months.

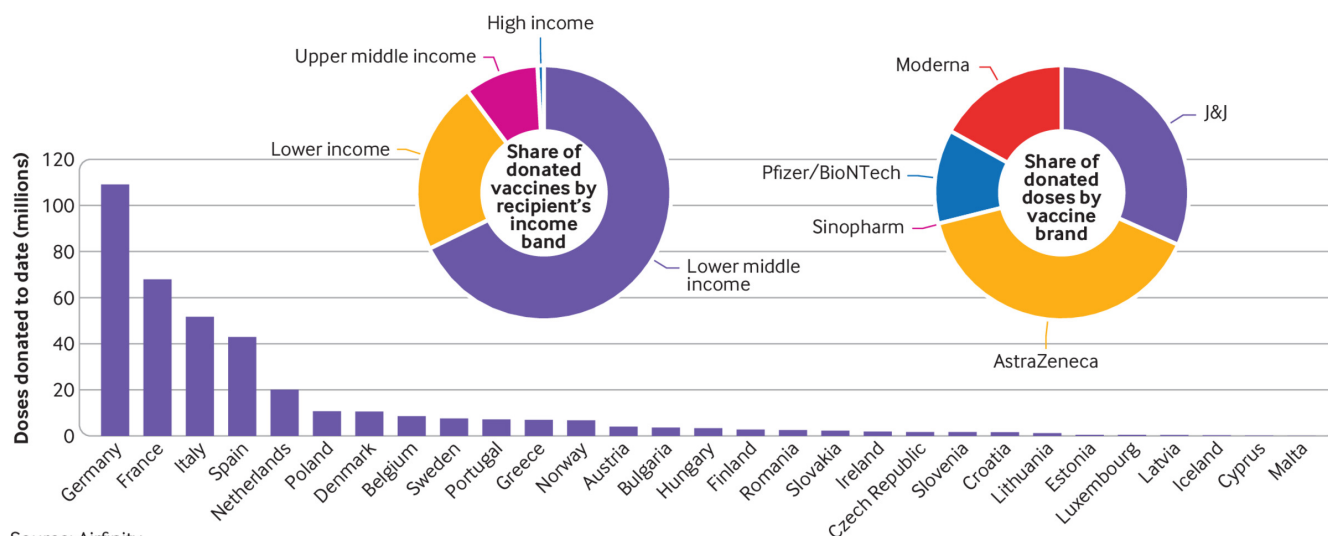
According to Reuters, more than 250 million doses left factories less than 10 weeks before they were due to expire, implying that the product was stuck in extensive quality checking procedures.⁶ A spokesperson from AstraZeneca declined to comment on why it still takes the company so long to release the finished products.

The Serum Institute of India, which is licensed to produce the AstraZeneca formulation under the brand name Covishield, has successfully extended the shelf life of the same vaccine. In June 2021, WHO approved the use of the Covishield vaccine for an extended nine months, but AstraZeneca itself has not submitted any application to WHO for a shelf life extension on its original vaccine. This is despite encouragement from WHO and the European Medicines Agency, a WHO spokesperson said. In April, following a decline in global demand, the Serum Institute of India announced it had stopped manufacturing the vaccine.

A representative from AstraZeneca said most of the vaccines leaving the company’s factories have a shelf life “of at least two and a half months.” She said the company is supporting government requests for shelf life extensions for “individual batches where viable” and in the meantime, AstraZeneca is in “a complex process involving the collection of real time data from 20 manufacturing partners” to extend the shelf life of the vaccine.

Meanwhile, developing countries are struggling to vaccinate as fast as they should, owing to a combination of logistical challenges, vaccine hesitancy, and misinformation among local populations. Airfinity told *The BMJ* that Africa currently has more doses of vaccine in stock than administered—about 265 million. And although less than 20% of Africa is vaccinated, South Africa’s vaccine manufacturing facility Aspen Pharmacare has yet to receive a single order,⁷ in part because countries are already flooded with expiring donated doses that they are struggling to use in time.

Faisal Shaibu, the Nigerian government official who oversaw one million doses ending up in a dump yard, says, “They should not have hoarded all these doses and only released them when they almost expired. If you donate these doses very late, this disrupts our systems.” Nigeria, he says, no longer accepts doses with short shelf lives.



Source: Airfinity

| EU/EEA donated doses per capita split by donor country, share of doses by recipient's income band and vaccine brand

This article is part of the series #FollowtheDoses, a cross border collaboration tracking covid-19 vaccine donations.

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