Unusual deal ensures Ebola vaccine supply

Drugmaker commits to stockpiling 300,000 doses and beginning approval process.

Erika Check Hayden

20 January 2016

Misha Hussain/Reuters

Much of the devastation wrought by Ebola in West Africa might have been prevented with a vaccine.

With the Ebola outbreak in West Africa stubbornly hanging on, officials have brokered an agreement to ensure that a vaccine is available to fight future occurrences. On 20 January, Gavi, the Vaccine Alliance, announced that it has paid US$5 million to Merck, the manufacturer of the first Ebola vaccine shown to protect against the virus in a human clinical trial. The deal marks the first time that the public-health organization has committed to purchase a vaccine before it has been licensed.

In return for the payment from Gavi, Merck promises that it will seek to have the vaccine approved by a regulatory agency by 2017. The company has also asked permission from the World Health Organization (WHO) to use the vaccine if another epidemic arises before the vaccine is licensed, and to make a supply of at least 300,000 doses available by May for such use.

“We wanted to make sure there was vaccine that was prepared and ready to be used if there was a potential outbreak,” says Seth Berkley, chief executive of Gavi in Geneva, Switzerland.

The recurrence of Ebola in Sierra Leone on 15 January — just one day after the WHO had declared that spread of the virus had stopped in West Africa — highlights the need for an Ebola vaccine stockpile, Berkley says. “It basically says we need to have a supply of vaccine available for potential outbreaks going forward, even if we get it completely under control and think we’ve ended the problem,” Berkley explains.

Public-health experts fear that as the West Africa epidemic winds down, there is danger that the work of stockpiling, licensing and planning to administer Ebola vaccines will be set aside in favour of more pressing — and profitable — pursuits.

“We are in the most tenuous situation with regard to Ebola vaccines that we’ve seen since we started all of this,” says Michael Osterholm, a public-health scientist at the University of Minnesota's Center for Infectious Disease Research and Policy in Minneapolis.

A vast store of Ebola vaccines has been manufactured in the past year — approximately 2 million doses of three candidate vaccines made by Merck, Johnson & Johnson and GlaxoSmithKline. So far, more than 20,000 people have been vaccinated with these products,

and thousands more will receive them in the coming months. Before the West Africa outbreak, only a handful of people had ever received a vaccination against Ebola. The existing supply should, at least in theory, be enough to provide crucial protection in a future outbreak for patients, their contacts and health-care workers, says Marie-Paule Kieny, assistant director-general for health systems and innovation at the WHO in Geneva.

Licensing barrier

But in practice, it remains unclear how those vaccines might be delivered during an outbreak. The biggest barrier is bureaucratic: none of the three vaccines has been submitted for approval by a regulatory body such as the US Food and Drug Administration or the European Medicines Agency. Sierra Leone and Guinea have made arrangements with the relevant companies to use the vaccines in clinical trials. But if Ebola were to arise elsewhere, negotiating similar agreements in new countries could delay the outbreak response.

Médecins Sans Frontières (MSF; also known as Doctors Without Borders), which administered the Merck vaccine trial in West Africa, plans to continue using the vaccines in investigative mode if another outbreak occurs. That means spending extra time and money compared with using a licensed vaccine — patients in a trial must be informed of the risk of taking an unapproved product, and providers must keep strict records of how well the vaccines work and whether they cause side effects. And if the vaccine is already known to be effective, this approach might also not be the right way to proceed from an ethical standpoint.

The Gavi agreement is intended to ease that problem by requiring Merck to seek an 'emergency use assessment and listing' — permission from the WHO to use the vaccine wherever it is needed without having to organize a clinical trial. Gavi says that Merck has already begun those discussions with the WHO, and that ultimately it might buy other vaccines if they are approved.

The deal also addresses a problem facing drug companies: Ebola and other tropical diseases still mainly afflict people in poor countries, so there is little financial incentive to produce vaccines against them. The funding from Gavi to Merck is an 'advance market commitment' — a guarantee that Gavi will buy the vaccine once it is approved. “It says the company is not going to be left holding the bag,” Berkley says.

Nature | doi:10.1038/nature.2016.19186