

MPOX VACCINE ACCESS

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Executive Summary

The world is reckoning with the second World Health Organization emergency declaration for mpox in as many years. A key tool to combat the virus, the MVA-BN mpox vaccine, owes its existence to two decades and billions of dollars worth of U.S. government investment. Despite profound public support, the vaccine's manufacturer, Bavarian Nordic, remains the sole supplier of MVA-BN and has done far too little to enable access to its vaccine outside of wealthy countries. The company has been reluctant to share its technology to expand global production and has kept its prices confidential. This report details U.S. support for MVA-BN and provides insight into the seemingly unique price offered to the U.S. government. Additionally, we identify global manufacturers that may be good candidates for technology transfer to produce MVA-BN globally.

The U.S. government pays an estimated price of \$55.35 per dose of MVA-BN. It therefore appears that the U.S. government pays less for MVA-BN than those purchasing the vaccine to serve the dire need in countries responding to mpox outbreaks. For example, publicly reported prices for the mpox response are as high as \$100 to \$141 per dose¹—amounting to between 1.8 and 2.5 times more than the estimated U.S. government price. Even the recently announced UNICEF price of up to \$65 per dose is higher than the estimated U.S. price.²

Bavarian Nordic should not charge poorer countries more than it charges rich countries. Moreover, the company should make its vaccine easily affordable for the global response, using cost-plus pricing. Bringing down prices would save millions of dollars that could be spent on other critical areas of the mpox response. Furthermore, secretive pricing hinders a coordinated response and gives no assurances that prices are fair. **Bavarian Nordic must publicly justify its pricing and disclose its costs.**

Further, Bavarian Nordic can license relevant technologies and work with manufacturers in LMICs, including in Africa, to enable sustainable access to MVA-BN. **Eight global manufacturers, five of which are located in LMICs, may be plausible candidates for technology transfer (based on their familiarity with production processes similar to those used by Bavarian Nordic to produce MVA-BN). All five LMIC manufacturers sold vaccines using similar processes as Bavarian Nordic for less than \$5 per dose—a fraction of Bavarian Nordic's mpox vaccine price.**

¹ Gabrielle Emanuel, *WHO Declares 2024 Mpox Surge a 'Public Health Emergency of International Concern'*, NPR (Aug. 14, 2024), <https://www.npr.org/sections/goats-and-soda/2024/08/14/g-s1-16977/mpox-public-health-emergency-world-health-organization-who>; Press Conference, WHO, WHO press conference on global health issues, at 41:30:00 (Sept. 4, 2024), <https://www.who.int/multi-media/details/who-press-conference-on-global-health-issues---4-september-2024#> (referencing the price of mpox vaccines at \$141 per dose).

² Press Release, UNICEF, UNICEF Signs Mpox Vaccine Deal at Lowest Market Price for 77 Low- and Lower-middle-income Countries (Sept. 26, 2024), <https://www.unicef.org/press-releases/unicef-signs-mpox-vaccine-deal-lowest-market-price-77-low-and-lower-middle-income>

The U.S. government has a long-standing relationship with Bavarian Nordic. **The U.S. government has provided over \$2.3 billion to Bavarian Nordic to support the development, licensure, and procurement of MVA-BN.** The government provided additional support for clinical trials and funding to establish U.S.-based fill-finish capacity. The U.S. should leverage its position with Bavarian Nordic to push the company to lower prices, share technology, and adopt a more transparent and public health-oriented approach.

Introduction

A key tool to contain mpox outbreaks exists because of U.S. government investment. The MVA-BN vaccine, manufactured by Bavarian Nordic as Jynneos, Imvamune, or Imvanex for the prevention of mpox and smallpox, has benefitted from decades of public support.

“The world has Jynneos because we invested in it,” U.S. Assistant Secretary for Preparedness and Response (ASPR), Dawn O’Connell, said in 2022.³ However, the vaccine remains inaccessible to much of the world. Despite substantial public support, Bavarian Nordic has done little to ensure affordability and access for communities where mpox is endemic or to contain new outbreaks in low- and middle-income countries (LMICs).

In August 2024, the Africa Centres for Disease Control and Prevention (Africa CDC) and the World Health Organization (WHO) declared mpox a public health emergency of continental security (PHEC) and a public health emergency of international concern (PHEIC), respectively.⁴ This is the second mpox-related PHEIC in two years. In July 2022, the WHO declared a PHEIC for mpox for a different outbreak that was spreading globally.⁵

During the global outbreak, no vaccines were available in Africa outside of a select few clinical trials. This was in part due to regulatory complexities and barriers to delivery. However, the 2022–3 response was also marked by inequity as wealthy countries purchased scarce vaccine supplies.⁶ At the time, advocates called on the Biden administration to develop a global plan to prevent the spread of mpox—urging the administration to heed lessons from Covid-19 and to prioritize equitable distribution of vaccines, tests, and treatments to countries experiencing outbreaks.⁷ Notably, in 2022, the manufacturer of the only FDA-approved mpox vaccine at the time, Bavarian Nordic, had closed its factory to expand its capacity to produce other vaccines, during which time no

³ Sharon LaFraniere, Noah Weiland, & Joseph Goldstein, *U.S. Could Have Had Many More Doses of Monkeypox Vaccine This Year*, N.Y. TIMES (Aug. 3, 2022) <https://www.nytimes.com/2022/08/03/us/politics/monkeypox-vaccine-doses-us.html>

⁴ *Africa CDC Declares Mpox A Public Health Emergency of Continental Security, Mobilizing Resources Across the Continent*, AFRICA CTRS. FOR DISEASE CONTROL & PREVENTION (Aug. 13, 2024), <https://africacdc.org/news-item/africa-cdc-declares-mpox-a-public-health-emergency-of-continental-security-mobilizing-resources-across-the-continent/>; *WHO Director-General Declares Mpox Outbreak a Public Health Emergency of International Concern*, WHO (Aug. 14, 2024), <https://www.who.int/news/item/14-08-2024-who-director-general-declares-mpox-outbreak-a-public-health-emergency-of-international-concern>

⁵ *Second Meeting of the International Health Regulations (2005) (IHR) Emergency Committee Regarding the Multi-country Outbreak of Monkeypox*, WHO (July 23, 2022), [https://www.who.int/news/item/23-07-2022-second-meeting-of-the-international-health-regulations-\(2005\)-\(ihr\)-emergency-committee-regarding-the-multi-country-outbreak-of-monkeypox](https://www.who.int/news/item/23-07-2022-second-meeting-of-the-international-health-regulations-(2005)-(ihr)-emergency-committee-regarding-the-multi-country-outbreak-of-monkeypox)

⁶ Zain Rizvi & Aly Bancroft, *Monkeypox Vaccine Shortage*, PUBLIC CITIZEN (Aug. 31, 2022), <https://www.citizen.org/article/monkeypox-vaccine-shortage/>

⁷ *Advocates Tell Biden: Develop Global Plan to Prevent Spread of Monkeypox*, PUBLIC CITIZEN (Aug. 19, 2022), <https://www.citizen.org/article/advocates-tell-biden-develop-global-plan-to-prevent-spread-of-monkeypox/>

new drug substance was produced — a reason in itself to enlist additional suppliers for the vaccine.⁸

While Bavarian Nordic’s factory is now functioning, and the WHO recently prequalified MVA-BN—a move that will help facilitate broader regulatory approval and accelerate procurement⁹—Bavarian Nordic remains the sole supplier of MVA-BN. The company has also kept its prices confidential and declined to discuss them in detail.¹⁰ In August 2024, Bavarian Nordic dismissed the suggestion that African governments might purchase vaccines at lower prices: “It’s very unlikely that any African country will ever be responsible for buying vaccines,” the company’s vice president of investor relations said, “[v]accines to Africa will come from donations from organizations and countries.”¹¹ Additionally, the company reportedly maintained that manufacturers in Africa would not be likely candidates to produce the vaccine.¹² A position that the company reversed just days later when it announced plans to work with the Africa CDC to partner with African manufacturers.¹³

Transparent communication about vaccine availability—through clear assurances of affordability and supply—is critically important during an emergency response. The WHO’s global mpox response plan highlights the urgent need to increase access to and delivery of mpox vaccines.¹⁴ The plan urges countries with vaccine stockpiles to make doses available and recommends that manufacturers review access and pricing policies to ensure vaccines are affordable and accessible in LMICs.¹⁵ The WHO also established an

⁸ Apoorva Mandavilli, *Will There Be Enough Monkeypox Vaccine?*, N.Y. TIMES (July 1, 2022), <https://www.nytimes.com/2022/07/01/health/monkeypox-vaccine-bavarian-nordic.html>

⁹ WHO *Prequalifies the First Vaccine Against Mpox*, WHO (Sept. 13, 2024), <https://www.who.int/news/item/13-09-2024-who-prequalifies-the-first-vaccine-against-mpox>

¹⁰ Helen Branswell, *To Counter Mpox, Vaccine Maker Could Ramp up by Another 8 Million Doses Next Year*, STAT (Aug. 16, 2024), <https://www.statnews.com/2024/08/16/bavarian-nordic-jynnneos-mpox-vaccine-maker-8-million-doses-next-year/>

¹¹ Elaine Ruth Fletcher, *Mpox Vaccine Manufacturing in Africa ‘Unlikely’, Donations as Most Likely Source, says Bavarian Nordic Official*, HEALTH POL’Y WATCH (Aug. 15, 2024), <https://healthpolicy-watch.news/mpox-vaccine-manufacturing-in-africa-unlikely-donations-are-most-likely-supply-channel-says-bavarian-nordic-official/>

¹² *Id.* (“Sørensen also ruled local African production of the Bavarian Nordic vaccine as technologically unfeasible. ‘We talk to producers around the world. We are not aware of any producers that can produce with our technology. So your scenario doesn’t seem realistic at all,’ he said.”).

¹³ News Release, Bavarian Nordic, *Bavarian Nordic Provides Statement on Mpox Vaccine Supply and Collaboration with African and Global Stakeholders* (Aug. 17, 2024), <https://www.bavarian-nordic.com/investor/news/news.aspx?news=6970>

¹⁴ WHO, *Mpox Global Strategic Preparedness and Response Plan*, at 9 (Sept. 6, 2024), <https://www.who.int/publications/m/item/mpox-global-strategic-preparedness-and-response-plan>

¹⁵ *Id.*

access and allocation mechanism to maximize use of scarce vaccine supplies and other medical tools through transparency and collaboration.¹⁶

A just mpox response demands that secret or unfair prices are not permitted to cause artificial scarcity. Bavarian Nordic has been far from transparent. The paucity of information around the company's pricing policies—such as the mention of a tiered pricing model, but with no specific details shared—provides little support to the WHO's vision for a coordinated emergency response.¹⁷

In September, the Biden-Harris administration committed one million mpox vaccines and \$500 million to assist mpox response efforts, a critically important contribution.¹⁸ The White House announcement again nodded to the U.S. government's essential role in bringing the MVA-BN vaccine to licensure and the importance of supporting local production.¹⁹ Yet despite substantial investments into MVA-BN, the U.S. government failed to secure contract terms that would enable reasonable pricing for LMICs or help facilitate sharing of technology with global manufacturers to expand supply. The U.S. government remains well-positioned to leverage its long-standing relationship with Bavarian Nordic to help ensure a more equitable mpox response.

In this report, we detail vaccine supply considerations, U.S. support for MVA-BN, and estimate the price offered to the U.S. government. Additionally, we identify global manufacturers that may be good candidates for technology transfer based on their use of similar production processes as Bavarian Nordic.

¹⁶ WHO and Partners Establish an Access and Allocation Mechanism for Mpox Vaccines, Treatments, Tests, WHO (Sept. 13, 2024), (<https://www.who.int/news/item/13-09-2024-who-and-partners-establish-an-access-and-allocation-mechanism-for-mpox-vaccines--treatments--tests>)

¹⁷ Kaamil Ahmed, *African Nations Hit by Mpox Still Waiting for Vaccines – Despite Promises by the West*, THE GUARDIAN (Sept. 1, 2024), (<https://www.theguardian.com/global-development/article/2024/sep/01/mpox-africa-vaccines-fail-to-arrive>)

¹⁸ The White House, *FACT SHEET: The United States Commitment to Address the Global Mpox Outbreak* (Sept. 24, 2024), (<https://www.whitehouse.gov/briefing-room/statements-releases/2024/09/24/fact-sheet-the-united-states-commitment-to-address-the-global-mpox-outbreak/>)

¹⁹ *Id.* (“ Since 2007, the United States, through the Department of Health and Human Services (HHS), has invested more than \$2 billion in the JYNNEOS vaccine as part of smallpox preparedness. Additionally, U.S. Government research institutions led the development of the JYNNEOS vaccine through preclinical evaluation, clinical trials, and advanced clinical evaluation platforms. These investments directly led to product licensure for both smallpox and mpox.”).

New Mpox Outbreaks, Continued Inequity

The world is reckoning with a second mpox PHEIC, this time sparked by the concerning upsurge in cases in the Democratic Republic of the Congo (DRC) and a growing number of countries in Africa, as well as the emergence of a new subtype of the virus that is spreading person-to-person, including through sexual networks.²⁰ In 2024, 31,427 total suspected mpox cases have been reported in Africa, with the large majority located in the DRC.²¹ Among these cases, 844 deaths were reported.²² Due to testing constraints, the subset of suspected cases that are confirmed to be mpox is lower (6,603).²³

As part of the mpox response, the WHO has estimated that, over six months, four million vaccine doses are needed for health workers and contacts of suspected cases.²⁴ The Africa CDC set a target to vaccinate 10 million people over six months.²⁵

African countries, including the DRC and Nigeria, have thus far received doses via donations from countries with stockpiles intended to prepare for smallpox threats or left over from the 2022–3 global mpox outbreak. About 275,460 MVA-BN doses have arrived in Africa.²⁶ This is less than 7% of the WHO's estimated dose requirement and between 1.4–2.8% of the Africa CDC's target (depending on whether one or two doses are used per person).²⁷ While the U.S., Japan, Canada, and several European countries have pledged to donate over four million additional vaccine doses, some donations remain uncertain and secured supply may still be less than what is needed to appropriately respond to the outbreaks in Africa.²⁸

²⁰ *First Meeting of the International Health Regulations (2005) Emergency Committee Regarding the Upsurge of Mpox 2024*, WHO (Aug. 19, 2024), [https://www.who.int/news/item/19-08-2024-first-meeting-of-the-international-health-regulations-\(2005\)-emergency-committee-regarding-the-upsurge-of-mpox-2024](https://www.who.int/news/item/19-08-2024-first-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-upsurge-of-mpox-2024)

²¹ *Mpox: Multi-country External Situation Report no.38*, WHO (Sept. 28, 2024), <https://www.who.int/publications/m/item/multi-country-outbreak-of-mpox--external-situation-report--38--28-september-2024>

²² *Id.*

²³ *Id.*

²⁴ WHO, *Mpox Global Strategic Preparedness and Response Plan*, at 17 (Sept. 6, 2024), <https://www.who.int/publications/m/item/mpox-global-strategic-preparedness-and-response-plan>

²⁵ Africa Ctrs. for Disease Control & Prevention, *Mpox Continental Preparedness and Response Plan for Africa*, at 21 (Sept. 5, 2024), <https://africacdc.org/download/mpox-continental-preparedness-and-response-plan-for-africa/>

²⁶ Chloe Searchinger & Allison Krugman, *Mpox Vaccine Tracker: Millions Pledged, Millions Still to Be Delivered*, THINK GLOB. HEALTH (Sept. 10, 2024), <https://www.thinkglobalhealth.org/article/mpox-vaccine-tracker-millions-pledged-millions-still-be-delivered>

²⁷ In supply-constrained outbreak situations, the WHO recommends “off-label” use of a single dose of MVA-BN. WHO *Prequalifies the First Vaccine Against Mpox*, WHO (Sept. 13, 2024), <https://www.who.int/news/item/13-09-2024-who-prequalifies-the-first-vaccine-against-mpox>

²⁸ The White House, *FACT SHEET: The United States Commitment to Address the Global Mpox Outbreak* (Sept. 24, 2024), <https://www.whitehouse.gov/briefing-room/statements-releases/2024/09/24/fact-sheet-the-united-states-commitment-to-address-the-global-mpox-outbreak/>; Chloe Searchinger & Allison Krugman, *Mpox Vaccine Tracker: Millions Pledged, Millions Still to Be Delivered*, THINK GLOB. HEALTH (Sept. 10, 2024),

In addition to donations from government smallpox and mpox stockpiles, Bavarian Nordic has stated that it could produce 2 million doses in 2024 and another 11 million by the end of 2025, provided orders are placed.²⁹ However, Bavarian Nordic's prices—reportedly set as high as \$100 to \$141 per dose³⁰—threaten to keep available supplies out of reach in LMICs and deplete limited funds needed for broader mpox response.³¹

Vaccine orders have been placed by UNICEF, which issued a tender for the procurement of mpox vaccines, and Gavi, the Vaccine Alliance (Gavi), which reportedly has up to \$500 million to put towards the mpox response, including to fund vaccine purchases.^{32,33} UNICEF announced that, building off discussions from Gavi's advance purchase agreement, it secured a price of up to \$65 per dose in its supply agreement for MVA-BN vaccines.³⁴ UNICEF's disclosure of the per dose price is notable. Bavarian Nordic has shown a concerning unwillingness to discuss its prices or pricing policies—tending to note only that price is dependent on volume and long-term commitment.³⁵ While the company has stated that it would be open to using tiered pricing, it has shared no details publicly on how prices would be set.³⁶

<https://www.thinkglobalhealth.org/article/mpox-vaccine-tracker-millions-pledged-millions-still-be-delivered>; Press Release, Ministry of Foreign Affairs of Japan, Signing and Exchange of Notes Regarding the Grant of Mpox Vaccines to the Democratic Republic of the Congo, (Sept. 18, 2024), https://www.mofa.go.jp/press/release/pressite_000001_00590.html

²⁹ News Release, Bavarian Nordic, Bavarian Nordic Provides Update on the Mpox Vaccine Supply Situation (Sept. 12, 2024), <https://www.bavarian-nordic.com/investor/news/news.aspx?news=6989>

³⁰ Gabrielle Emanuel, *WHO Declares 2024 Mpox Surge a 'Public Health Emergency of International Concern'*, NPR (Aug. 14, 2024), <https://www.npr.org/sections/goats-and-soda/2024/08/14/g-s1-16977/mpox-public-health-emergency-world-health-organization-who>; Press Conference, WHO, WHO press conference on global health issues, at 41:30:00 (Sept. 4, 2024), <https://www.who.int/multi-media/details/who-press-conference-on-global-health-issues---4-september-2024#> (referencing the price of mpox vaccines at \$141 per dose).

³¹ *Letter Urging Gavi, UNICEF to Negotiate Fair Price of Mpox Vaccines*, PUBLIC CITIZEN (Aug. 27, 2024), <https://www.citizen.org/article/letter-urging-gavi-unicef-to-negotiate-fair-price-of-mpox-vaccines/>

³² Press Release, UNICEF, UNICEF Issues Emergency Tender to Secure Mpox Vaccines for Crisis-hit Countries in Collaboration with Africa CDC, Gavi and WHO (Aug. 31, 2024), <https://www.unicef.org/press-releases/unicef-issues-emergency-tender-secure-mpox-vaccines-crisis-hit-countries>

³³ Jennifer Rigby, *Mpox: Vaccine Group Gavi Says It Has up to \$500 million for Shots*, REUTERS (Aug. 16, 2024), <https://www.reuters.com/business/healthcare-pharmaceuticals/vaccine-group-gavi-has-up-500-million-funds-mpox-shots-2024-08-15/>

³⁴ Press Release, UNICEF, UNICEF Signs Mpox Vaccine Deal at Lowest Market Price for 77 Low- and Lower-middle-income Countries (Sept. 26, 2024), <https://www.unicef.org/press-releases/unicef-signs-mpox-vaccine-deal-lowest-market-price-77-low-and-lower-middle-income>

³⁵ Helen Branswell, *To Counter Mpox, Vaccine Maker Could Ramp up by Another 8 Million Doses Next Year*, STAT (Aug. 16, 2024), <https://www.statnews.com/2024/08/16/bavarian-nordic-jynneos-mpox-vaccine-maker-8-million-doses-next-year/>

³⁶ Kaamil Ahmed, *African Nations Hit by Mpox Still Waiting for Vaccines – Despite Promises by the West*, THE GUARDIAN (Sept. 1, 2024), <https://www.theguardian.com/global-development/article/2024/sep/01/mpox-africa-vaccines-fail-to-arrive>

Bavarian Nordic's approach to access and pricing for its vaccine is concerning for a few key reasons.

First, public funding undergirds the MVA-BN vaccine. Since 2003, the U.S. government, primarily via the National Institutes of Health (NIH) and the Biomedical Advanced Research and Development Authority (BARDA), within the Health and Human Services' (HHS') Administration of Strategic Preparedness and Response (ASPR), has committed over \$2.3 billion to support the development, licensure, and purchase of Bavarian Nordic's smallpox/mpox vaccine. Despite critical investments from the U.S., Bavarian Nordic retained sole control over the vaccine's production, supply, and price.

Second, without clear access and affordability assurances, demand may be artificially restricted. As case detection efforts improve and response efforts develop, the amount of vaccines needed over the first six months and through 2025 may increase. To realistically plan the mpox response, national governments, the Africa CDC, the WHO, and others making vaccination plans need a clear picture of the vaccine supply available to them. Although Bavarian Nordic has indicated it can supply 13 million doses through 2025, the high price of the vaccine may prevent purchasers from procuring sufficient quantities. Clear access and affordability assurances from Bavarian Nordic can provide greater certainty about supply availability, in turn helping governments and organizations plan accordingly and continue to invest in the capacity to deploy vaccines as needed.

Third, considering the continued spread of mpox, the world cannot rely on a single supplier for a key vaccine. Bavarian Nordic must share its technology to ensure equitable and sustainable access. Although MVA-BN was first approved for mpox in 2019, it was not until recently that Bavarian Nordic appeared to consider how to enable supply for outbreaks in LMICs or in countries where mpox has been endemic for decades.³⁷ Bavarian Nordic should share technology and know-how with manufacturers in LMICs. Doing so can help scale up low-cost production for current and future outbreaks.

³⁷ Elaine Ruth Fletcher, *Mpox Vaccine Manufacturing in Africa 'Unlikely', Donations as Most Likely Source, says Bavarian Nordic Official*, HEALTH POL'Y WATCH (Aug. 15, 2024), <https://healthpolicy-watch.news/mpox-vaccine-manufacturing-in-africa-unlikely-donations-are-most-likely-supply-channel-says-bavarian-nordic-official/>; Kerry Cullinan, *Africa CDC in Talks with Bavarian Nordic to Bring Mpox Vaccine Production to the Continent*, HEALTH POL'Y WATCH (Aug. 20, 2024), <https://healthpolicy-watch.news/africa-cdc-in-talks-with-bavarian-nordic-to-bring-mpox-vaccine-production-to-the-continent/>

U.S. Support for MVA-BN

Bavarian Nordic’s smallpox/mpox vaccine can trace its origins to a vaccine developed by German public scientists more than half a century ago.³⁸ Public science and public funding in Germany and the U.S. undergirded the development of the vaccine now under Bavarian Nordic’s sole control.³⁹

The U.S. first invested in Bavarian Nordic’s smallpox vaccine in the wake of the September 11th and anthrax attacks. As described by Rizvi (2022):

The September 11 and anthrax attacks led to a new sense of urgency. The U.S. was gripped by fears about bioterrorism. Topping the list was the release of the smallpox virus—one of the deadliest pathogens in human history. Shortly after 9/11, Anthony Fauci and the NIH met with Bavarian Nordic. The NIH sponsored a regulatory application with Bavarian Nordic and, in 2003, the agency formally began bankrolling the development of MVA-BN for smallpox. Once again, it was public money pushing this work forward—though through a private intermediary.

...

The U.S. government—primarily through the NIH and Biomedical Advanced Research and Development Authority (BARDA)—funded clinical studies, dose purchases, new formulation development, and even the qualification of a new production facility.⁴⁰

Public records show that the U.S. has awarded more than \$2.3 billion to Bavarian Nordic to support MVA-BN. [Table 1]

Table 1. U.S. Government Support for MVA-BN (Jynneos/Imvamune/Imvanex)

Agency	Contract Number	Scope	Years	Amount ⁴¹
NIH	00266200302D266030016	Development & testing (preclinical work, clinical trials). ⁴²	2003-2009	\$10,860,308.00
	HHSN266200400072C	Production & testing (Clinical trials; 500,000)	2004-2015	\$115,773,474.42

³⁸ For a detailed history, see Zain Rizvi, *How a Danish Company Grabbed Control of the Monkeypox Vaccine*, THE AMERICAN PROSPECT (Sept. 22, 2022), <https://prospect.org/health/how-danish-company-grabbed-control-of-monkeypox-vaccine/>

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ *Bavarian Nordic Prime Awards*, USASPENDING.GOV, <https://www.usaspending.gov/search/?hash=5dde72b8aab4c09b5cdf3abf5f237789> (last visited Sept. 20, 2024).

⁴² News Release, U.S. Dep’t Health & Hum. Servs., HHS Announces Contracts to Develop Safer Smallpox Vaccines (Feb. 25, 2003), <https://web.archive.org/web/20030402090421/http://www.hhs.gov/news/press/2003pres/20030225.html>

Agency	Contract Number	Scope	Years	Amount ⁴¹
		doses; Validation of animal models). ⁴³		
BARDA/ASPR	HHSO100200700034C	Procurement of 28M doses for the stockpile; Clinical trials; Production of bulk vaccine. ⁴⁴	2007-2017	\$1,010,761,647.00
	HHSO100201000011C	Development of freeze-dried formulation; Validation of freeze-dried production process. ⁴⁵	2009-2017	\$75,033,696.00
	HHSO100201700019C	Clinical trial; Production of bulk vaccine; Procurement for the stockpile and mpox outbreak; Qualification of new fill/finish facility. ⁴⁶	2017-2027	\$1,023,713,981.00
FDA	N/A	Priority Review Voucher upon approval of Jynneos, later sold by the company. ⁴⁷	2019	\$95,000,000
Total				\$2,331,143,106.42

Additional Support

Rivzi (2022) noted that, in addition to direct support provided to Bavarian Nordic, “[m]illions more was likely spent supporting independent clinical studies run by the NIH and CDC,” and characterized further support:

⁴³ News Release, U.S. Dep’t Health & Hum. Servs., HHS Awards \$232 Million in Biodefense Contracts for Vaccine Development (Oct. 7, 2004), <https://web.archive.org/web/20041031155630/http://www.hhs.gov/news/press/2004pres/20041007a.html>; Bavarian Nordic Announces Significant Progress In Safe Smallpox Vaccine (Oct. 19, 2005), available at: <https://www.biospace.com/bavarian-nordic-announces-significant-progress-in-safe-smallpox-vaccine>; BAVARIAN NORDIC, 2006 ANNUAL REPORT 21 (Mar. 30, 2007), available at: <https://www.globenewswire.com/en/news-release/2007/03/30/103225/0/en/Bavarian-Nordic-A-S-Annual-Report-2006.html>

⁴⁴ News Release, U.S. Dep’t Health & Hum. Servs., HHS Buys Next Generation Smallpox Vaccine (June 4, 2007), <https://web.archive.org/web/20140103162120/http://www.hhs.gov/news/press/2007pres/06/20070604a.html>; Bavarian Nordic, 2016 Form F-1/A1, at 111, <https://www.sec.gov/Archives/edgar/data/1576915/000104746916009636/a2227062zf-1a.htm>

⁴⁵ *Id.*

⁴⁶ News Release, Bavarian Nordic, Bavarian Nordic Secures Contract Award for Supply of Freeze-Dried Imvamune Smallpox Vaccine to the U.S. Government (Sept. 27, 2017), <https://www.bavarian-nordic.com/investor/news/news.aspx?news=5322>; News Release, Bavarian Nordic, Bavarian Nordic Announces Exercise of USD 44 Million Option by the U.S. Government Under Contract for Freeze-Dried Mva-Bn® Smallpox Vaccine (Jan. 18, 2019), <https://www.bavarian-nordic.com/investor/news/news.aspx?news=5560>; *Synopsis for Increase in Contract Ceiling - BN*, SAM.GOV (Aug. 12, 2022) <https://sam.gov/opp/10d16af3602e48d29eca6cd3dadad865/view>

⁴⁷ News Release, Bavarian Nordic, Bavarian Nordic Announces Closing of Sale of Priority Review Voucher (Jan. 27, 2020), <https://www.bavarian-nordic.com/investor/news/news.aspx?news=5899>

Aside from financing, the U.S. government has carried out its own research directly. In 2015, Army scientists, subsidized indirectly by BARDA, ran a pivotal clinical trial comparing the immune response from Jynneos to a traditional smallpox vaccine in U.S. service members stationed in South Korea. It was also U.S. officials who first raised the possibility of getting Jynneos authorized for monkeypox, because the two viruses are similar. Bavarian Nordic did not initially request such regulatory authorization.⁴⁸

The U.S. government has most recently sponsored clinical trials to evaluate dose-sparing strategies and use of MVA-BN in adolescents—the data from the latter Bavarian Nordic recently submitted to the European Medicines Agency to extend the vaccine’s use to broader populations.⁴⁹ [Table 2]

Table 2. Indirect Support via Clinical Trials

Agency	Clinical Trial Number	Scope	Years
NIH	NCT00082446	Phase 1 evaluating safety & immunogenicity.	2004–2007
	NCT00189904	Phase 1/2 evaluating safety & immunogenicity in patients with HIV.	2005–2007
	NCT00437021	Phase 2 evaluating safety & immunogenicity.	2007–2009
	NCT00879762	Phase 2 to evaluate high dose.	2009–2011
	NCT00914732	Phase 2 to evaluate freeze-dried formulation.	2010–2011
	NCT01827371	Phase 2 to evaluate immunization schedules, modes of delivery.	2013–2015
	NCT05512949	Phase 2 to evaluate intradermal delivery to expand vaccine supply.	2022–2023
	NCT05740982	Phase 2 to evaluate use in adolescents.	2023–2024
	NCT05734508	Phase 4 study in the DRC.	2023–2024
U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)	NCT01913353	Phase III trial in South Korea.	2015–2017
CDC	NCT02977715	Phase III trial in the DRC.	2017–2025

Additionally, the U.S. government provided support to establish U.S.-based fill-finish capacity for MVA-BN. In 2022, when Bavarian Nordic’s supply capacity was limited, HHS facilitated an agreement between Bavarian Nordic and a U.S.-based contract manufacturer.⁵⁰ HHS further contributed \$11 million to the contract manufacturer to

⁴⁸ Zain Rizvi, *How a Danish Company Grabbed Control of the Monkeypox Vaccine*, THE AMERICAN PROSPECT (Sept. 22, 2022), <https://prospect.org/health/how-danish-company-grabbed-control-of-monkeypox-vaccine/>

⁴⁹ News Release, Bavarian Nordic, Bavarian Nordic Receives WHO Prequalification for Mpox Vaccine (Sept. 13, 2024), <https://www.bavarian-nordic.com/investor/news/news.aspx?news=6990>

⁵⁰ News Release, U.S. Dep’t Health & Hum. Servs., HHS Facilitates Agreement to Accelerate Delivery of Additional Smallpox and Monkeypox Vaccines Using New U.S. Production Line (Aug. 18, 2022) <https://www.hhs.gov/about/news/2022/08/18/hhs-facilitates-agreement-accelerate-delivery-additional-smallpox-monkeypox-vaccines-using-new-us-production-line.html>

accelerate the tech transfer process.⁵¹ This contribution of federal funds helped set up domestic capacity in four months, instead of the nine-month timeline typical of such processes.⁵² This facility appears to make up a portion of Bavarian Nordic's current overall capacity.⁵³

MVA-BN Commercial Launch

During the 2022–3 global outbreak, the MVA-BN mpox vaccine was deployed in the U.S. from supplies in the Strategic National Stockpile. While the mpox emergency declaration in the U.S. ended in 2023, the vaccine is now recommended by the U.S. CDC Advisory Committee on Immunization Practices (ACIP) for routine use (as opposed to use only during outbreak response) for those 18 years or older at risk of mpox.⁵⁴ ACIP's recommendation, along with a new-found market for mpox vaccines, paved the way for Bavarian Nordic to launch MVA-BN on the commercial market.⁵⁵ As an ACIP-recommended vaccination, the vaccine is covered for routine use in at-risk adults under Medicare and Medicaid and available to uninsured and underinsured at-risk adults through certain publicly supported programs.⁵⁶ Under CDC contracts with Bavarian Nordic, the vaccine costs \$229.50 per dose.⁵⁷ The private sector list price is \$270 per dose.⁵⁸ The price under CDC contracts is therefore around four times more than the price that BARDA pays to stockpile MVA-BN.

⁵¹ News Release, U.S. Dep't Health & Hum. Servs., HHS Funds U.S.-Based Production of Smallpox and Monkeypox Vaccine (Aug. 29, 2022), <https://www.hhs.gov/about/news/2022/08/29/hhs-funds-us-based-production-of-smallpox-and-monkeypox-vaccine.html>

⁵² *Id.*; News Release, Grand River Aseptic Manufacturing, Grand River Aseptic Manufacturing Receives Zero Observations from FDA Inspection, Aiding in the Supply of Bavarian Nordic's JYNNEOS® (Mar. 17, 2023), <https://www.grandriverasepticmfg.com/news/grand-river-aseptic-manufacturing-receives-zero-observations-from-fda-inspection-aiding-in-the-supply-of-bavarian-nordics-jynneos/>

⁵³ Helen Branswell, *To Counter Mpox, Vaccine Maker Could Ramp up by Another 8 Million Doses Next Year*, STAT (Aug. 16, 2024), <https://www.statnews.com/2024/08/16/bavarian-nordic-jynneos-mpox-vaccine-maker-8-million-doses-next-year/>

⁵⁴ *ACIP Recommendations*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/acip/vaccine-recommendations/?CDC_AAref_Val=https://www.cdc.gov/vaccines/acip/recommendations.html

⁵⁵ The vaccine launched on the U.S. commercial market in April 2024. News Release, Bavarian Nordic, Bavarian Nordic Announces Commercial Launch of Mpox Vaccine in the U.S. (Apr. 2, 2024), <https://www.bavarian-nordic.com/investor/news/news.aspx?news=6931>

⁵⁶ *Mpox Update: Clinical Management and Outbreaks*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, at 38–40 (June 27, 2024), https://emergency.cdc.gov/coca/ppt/2024/062724_transcript.pdf

⁵⁷ *Current CDC Vaccine Price List*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/vaccines-for-children/php/awardees/current-cdc-vaccine-price-list.html> (last visited Sept. 20, 2024).

⁵⁸ *Id.*

The BARDA Price

BARDA appears to pay a unique price for MVA-BN. In 2016, Bavarian Nordic wrote in a filing to the U.S. Securities and Exchange Commission that BARDA paid \$29 per dose⁵⁹—notably lower than the current prices reportedly ranging from \$65 to \$100-plus per dose. Due to a lack of transparency, the current price paid by BARDA is unknown.

To estimate more recent pricing offered to BARDA, we reviewed publicly available information on vaccine procurement, including contract award details disclosed online and news releases from U.S. government agencies and Bavarian Nordic.

During the 2022–3 global mpox outbreak, the U.S. purchased liquid-frozen doses of MVA-BN. However, these doses were filled using government-owned bulk vaccine stored at Bavarian Nordic’s facility until filling and delivery.⁶⁰ As information from the 2022 outbreak only discloses the amount paid for finished doses but not for government-owned bulk, we cannot directly estimate a total per-dose price.

To help estimate the per dose price, we aggregated the total cost of: (1) filling and finishing each dose with (2) prior government-owned bulk, presented as a per dose price (this was estimated by converting the number of approximate dose equivalents per batch of bulk vaccine). We used publicly available information on orders for filled doses placed in 2022, as well as information regarding the purchase of bulk drug substance (BDS) batches, to estimate the total price that BARDA pays for each vaccine dose.

We estimate that BARDA pays about **\$55.35 per dose of liquid-frozen MVA-BN**. This estimate is based on the finding that in 2022, the U.S. paid about \$31.64 per dose filled from government-owned bulk, combined with the estimate that the U.S. pays \$23.71 per dose equivalent of bulk. [Table 3]

Table 3. Estimated BARDA Price Per Dose

Vaccine Form	Number of Bulk Drug Substance (BDS) Batches	Amount Paid	Number of Doses	Price Per Dose (or per dose equivalent of bulk)
Bulk Vaccine	35	\$83,000,000 ⁶¹	3,500,000 ⁶²	\$23.71

⁵⁹ Bavarian Nordic, 2016 Form F-1/A1, at 83,

<https://www.sec.gov/Archives/edgar/data/1576915/000104746916009636/a2227062zf-1a.htm>

⁶⁰ News Release, U.S. Dep’t Health & Hum. Servs., HHS Orders 2.5 Million More Doses of JYNNEOS Vaccine For Monkeypox Preparedness (July 1, 2022), <https://www.hhs.gov/about/news/2022/07/01/hhs-orders-2-point-5-million-more-doses-jynneos-vaccine-for-monkeypox-preparedness.html>

⁶¹ BAVARIAN NORDIC, 2021 ANNUAL REPORT 78 (Mar 4, 2022), https://www.bavarian-nordic.com/media/314126/bn_annual_report_2021.pdf (“...BARDA committed to an additional USD 83 million for the procurement of 35 BDS batches...”).

⁶² i.e. converting the number of BDS batches to an equivalent number of doses. 1 BDS is equivalent to about 100,000 doses. *J&A Procurement of Smallpox (Mpox) Vaccine for the Strategic National Stockpile*, SAM.GOV (Apr. 4, 2023), <https://sam.gov/opp/3272500464df4074bcf512146f1f5fec/view> (“As of May 2022, BARDA owned **164 batches of BDS (~16.4M dose equivalents)** ... BARDA exercised several contract options (June - July 2022)

Vaccine Form	Number of Bulk Drug Substance (BDS) Batches	Amount Paid	Number of Doses	Price Per Dose (or per dose equivalent of bulk)
Filled Dose	N/A	\$174,000,000 ⁶³	5,500,000	\$31.64
Total				\$55.35*

*This estimate is limited by a lack of transparency. The precise amount paid and number of dose-equivalents per BDS batch are not known; therefore, all numbers used in our estimate are approximate. Additionally, we could not ascertain whether the amount paid for bulk vaccine includes payment for storage at Bavarian Nordic’s facility, in which case, the amount paid per dose equivalent of bulk would be lower. Finally, it is possible that costs are not aggregated in this way for the purchase of bulk and finished doses. Noting the limitations of this estimate, **the U.S. government should disclose the price it pays for MVA-BN to confirm that LMICs and those purchasing on their behalf are not asked to pay more than the U.S.**

At the \$100–\$141 per dose prices circulating in public reports, Bavarian Nordic would be charging between 1.8 and 2.5 times more than it charges the U.S. government. The \$65 per dose price disclosed by UNICEF is much closer to the estimated BARDA price, though it is still notably higher. Offering MVA-BN at the BARDA price or lower would therefore save millions of dollars that could be spent on other critical areas of the mpox response. [Table 4]

Table 4. Cost by Doses Purchased

Per Dose Price	Cost by Doses Purchased					
	500,000	1 million	2 million	3 million	4 million	5 million
\$31.64 (BARDA filled dose price)	\$15.82 million	\$31.64 million	\$63.28 million	\$94.92 million	\$126.56 million	\$158.2 million
\$55.35 (Est. total BARDA price)	\$27.675 million	\$55.35 million	\$110.7 million	\$166.05 million	\$221.4 million	\$276.75 million
\$65	\$32.5 million	\$65 million	\$130 million	\$195 million	\$260 million	\$325 million
\$100	\$50 million	\$100 million	\$200 million	\$300 million	\$400 million	\$500 million
\$141	\$70.5 million	\$141 million	\$282 million	\$423 million	\$564 million	\$705 million

to utilize existing BDS (55 batches ordered; 109 batches remain) to support the fill/finish of 5.5M doses”) (emphasis added).

⁶³ BARDA placed 3 orders for filled doses in 2022. One for 500,000 doses and two more for 2.5 million doses each. The U.S. paid a total of ~\$174 million for these orders. *J&A Procurement of Smallpox (Mpox) Vaccine for the Strategic National Stockpile*, SAM.GOV (Apr. 4, 2023),

<https://sam.gov/opp/3272500464df4074bcf512146f1f5fec/view> (“In response to the increasing number of cases of monkeypox within the US and globally, BARDA exercised several contract options ... to support the fill/finish of 5.5M doses of liquid frozen JYNNEOS vaccine at a total costs of \$174M.”).

Moreover, as UNICEF announced that it had negotiated a price of “up to” \$65 per dose, it therefore appears that the final price could be lower.

Bavarian Nordic should not charge poorer countries more than it charges rich countries. Moreover, the company should make its vaccine easily affordable for the global response, using cost-plus pricing. To ensure a fair price, Bavarian Nordic must publicly justify its pricing and disclose its costs.

Further, increased revenues and long-term contracts for government stockpiles should give the company more flexibility to provide lower prices for LMICs. In 2023, Bavarian Nordic’s revenue from MVA-BN increased 190% compared to the previous year.⁶⁴ BARDA and the Public Health Agency of Canada—both long-term stockpiling customers⁶⁵—made up over 45% of Bavarian Nordic’s total revenue that year.⁶⁶

⁶⁴ BAVARIAN NORDIC, 2023 ANNUAL REPORT 14 (Mar. 6, 2024), <https://www.bavarian-nordic.com/investor/annual-report-2023.aspx>

⁶⁵ BARDA entered a 10-year contract with Bavarian Nordic in 2017 and has placed recent orders to procure bulk vaccine and freeze-dried doses. The Public Health Agency of Canada entered a 10-year contract with Bavarian Nordic in 2022. *See* News Release, Bavarian Nordic, Bavarian Nordic Awarded USD 63 Million from the U.S. Government for Production and Supply of Additional Smallpox/Mpox Vaccines (Sept. 24, 2024) <https://www.bavarian-nordic.com/media/media/news.aspx?news=7001>; News Release, Bavarian Nordic, Bavarian Nordic Awarded Ten-Year Contract Amendment valued up to USD 434 million for the Supply of Smallpox and Monkeypox Vaccine to Canada (Sept. 20, 2022), <https://www.bavarian-nordic.com/investor/news/news.aspx?news=6646>

⁶⁶ *Id.* at 59.

Global Manufacturing

After prompting from the Africa CDC and others, Bavarian Nordic has finally begun discussions with a manufacturer in Africa to establish fill-finish capacity in the region.⁶⁷ While this can help to increase supply and lower prices, it may not be sufficient to meet local needs or support self-sufficient local manufacturing. Doing so would require Bavarian Nordic to share technology, including biological resources, know-how, and patents.⁶⁸ To adequately facilitate expanded production of MVA-BN, Bavarian Nordic should publicly disclose patent claims relevant to MVA-BN's production and should license relevant patents.

In 2022, Public Citizen published an analysis of global vaccine manufacturers with experience in production processes similar to that used by Bavarian Nordic to produce MVA-BN (i.e. products using chick embryo fibroblast, or CEF, cells central to Jynneos production).⁶⁹ The purpose of this analysis was to identify manufacturers that could be suitable candidates for technology and know-how transfer to increase production of the MVA-BN mpox vaccine.

The report concluded that the manufacturers identified likely possess knowledge that would allow them to learn how to produce the vaccine faster than other manufacturers. They may also have established supply chains for key materials, like specific pathogen-free eggs, that could be drawn upon to expand production. Additionally, LMIC manufacturers have a different cost structure, including for raw materials and labor, that could help lower the price of vaccines, increasing demand and making doses more accessible.

Considering the current mpox PHEIC, we updated this analysis. We systematically reviewed regulatory records for vaccines approved by the FDA and vaccines prequalified by the WHO since 2022 to find any new products that used chick embryo fibroblast cell cultures. We found none. We conducted additional searches using “chick embryo fibroblast” AND “vaccine” in Google and PubMed, which yielded two CEF-based vaccines.

The first is a measles vaccine from Beijing Minhai Biotechnology Co, Ltd. and the National Institute of Health in Islamabad, Pakistan.⁷⁰ The Institute states the vaccine fulfills WHO

⁶⁷ Africa CDC confident it can raise \$600 million for mpox response, REUTERS (Sept. 12, 2024), <https://www.reuters.com/business/healthcare-pharmaceuticals/africa-cdc-confident-it-can-raise-600-million-mpox-response-2024-09-12/>

⁶⁸ Public Citizen has previously documented know-how and patent barriers to scaling up global production of MVA-BN. See Zain Rizvi, PUBLIC CITIZEN, RAMPING UP MPXV VACCINE PRODUCTION (Nov. 1, 2022), <https://www.citizen.org/article/ramping-up-mpxv-vaccine-production/>

⁶⁹ Zain Rizvi, PUBLIC CITIZEN, RAMPING UP MPXV VACCINE PRODUCTION (Nov. 1, 2022), <https://www.citizen.org/article/ramping-up-mpxv-vaccine-production/>

⁷⁰ Biological Production Division, *Viral Vaccines*, NAT'L INST. HEALTH PAKISTAN, <https://bpd.nih.org.pk/products/viral/>

requirements for Measles Vaccine (Live), but we were unable to locate any other information from WHO records. Without additional verification, we refrained from including it in our update. The second vaccine treats Kyasanur Forest Disease and was produced by the Government of Karnataka in India, but is no longer licensed for use and was excluded on that basis.⁷¹ Additionally, we excluded one candidate that has not yet completed phase 3 trials but has validated a CEF-based manufacturing process.⁷²

South African manufacturer, Biovac, reportedly supplied an MMR vaccine manufactured using CEF.⁷³ However, we could not confirm whether Biovac had experience propagating viruses using CEF for this vaccine. Additionally, Biovac no longer supplies this vaccine. Thus, it was excluded.

In sum, the eight manufacturers identified below are the most plausible candidates (based on their familiarity with CEF production processes) to receive technology transfer from Bavarian Nordic in order to scale up global supply of mpox vaccines. Five of those manufacturers are in LMICs, all of which sell vaccines for less than \$5 per dose. [Table 5]

Table 5. Manufacturers with CEF Experience

Manufacturer	Location	CEF-Based Product	FDA Approval or WHO PQ	Public Prices
GlaxoSmithKline (GSK)	Belgium	Measles and mumps virus used in Measles, Mumps, Rubella (MMR) vaccine (Priorix) ⁷⁴	Y	\$4.47 ⁷⁵ (UNICEF)

⁷¹ G T Sathish, *Girl's Death in Karnataka Owing to Kyasanur Forest Disease Intensifies Need for Vaccine*, THE HINDU (Jan. 12, 2024), <https://www.thehindu.com/news/national/karnataka/girls-death-owing-to-kfd-intensifies-need-for-vaccine/article67726754.ece>; Seema Prasad, *2024 Peak Year for Kyasanur Forest Disease, Karnataka Health Officials Confirm as Cases Rise*, DOWN TO EARTH (Feb.12, 2024), <https://www.downtoearth.org.in/health/2024-peak-year-for-kyasanur-forest-disease-karnataka-health-officials-confirm-as-cases-rise-94403>

⁷² Press Release, GeoVax Labs, Inc., *GeoVax Achieves Milestone in Transition to Commercially Validated Manufacturing System* (Mar. 6, 2024), <https://geovax.com/investors/press-releases/geovax-achieves-milestone-in-transition-to-commercially-validated-manufacturing-system>

⁷³ Adele Visser, *Combination Vaccines in the South African Setting*, [https://repository.up.ac.za/bitstream/handle/2263/20793/Visser_Combination\(2012\).pdf?sequence=1](https://repository.up.ac.za/bitstream/handle/2263/20793/Visser_Combination(2012).pdf?sequence=1) (“Measles virus (Schwarz strain in chick embryo cell line); Mumps virus (Urabe AM9 strain in chick embryo cell line”). Beyond formulary listings from 2012, we could not confirm additional details about Biovac’s capacity related to CEF.

⁷⁴ Priorix Package Insert, WHO, https://extranet.who.int/prequal/sites/default/files/vwa_vaccine/pq_62_252_MMR_GSK_PI_2022.pdf (“produced in chick embryo cells”).

⁷⁵ *Measles, mumps and rubella vaccine (MMR) price data*, UNICEF, <https://www.unicef.org/supply/media/20206/file/MMR-vaccine-prices-06122023.pdf> (price in 2023).

Manufacturer	Location	CEF-Based Product	FDA Approval or WHO PQ	Public Prices
Bio-Manguinhos/Fiocruz	Brazil	Measles and mumps virus used in MMR vaccine ⁷⁶	N ⁷⁷	–
Chiron Behring Vaccines (Bharat Biotech)	India	Rabies virus used in vaccine (Chirorab) ⁷⁸	N ⁷⁹	\$4.77 ⁸⁰
Serum Institute of India	India	Mumps virus used in MMR vaccine ⁸¹	Y	\$1.71-3.56 ⁸² (UNICEF)
Zydus Cadila	India	Rabies virus used in vaccine (VaxiRab N) ⁸³	Y	\$4.77 ⁸⁴ (India)
PT Bio Farma	Indonesia	Measles virus used in vaccine ⁸⁵	Y	\$0.31 ⁸⁶ (UNICEF)

⁷⁶ Bio-Manguinhos received a full technology transfer from GSK to manufacture the MMR product, which relies on CEF. *Triple Viral*, FIOCRUZ (May 20, 2024), <https://www.bio.fiocruz.br/index.php/br/produtos/vacinas/triplice-viral>; ANVISA Filing, (“A vacina sarampo, caxumba, rubéola (atenuada) é uma preparação mista liofilizada das cepas de vírus atenuados de sarampo (Schwarz), caxumba (RIT 4385 – derivada da cepa Jeryl Lynn) e rubéola (Wistar RA 27/3), e, separadamente obtidas por propagação em culturas de tecido de ovos embrionados de galinha (sarampo e caxumba) ou células diplóides humanas MRC-5 (rubéola).”).

⁷⁷ Bio-Manguinhos has a prequalified yellow fever vaccine. *Yellow Fever*, WHO, <https://extranet.who.int/prequal/vaccines/p/yellow-fever>

⁷⁸ Press Release, Chiron Behring Re-Launches It’s Rabies Vaccine as “Chirorab®” (Nov. 14, 2019), [ChiroRab-Press-Release-Nov-13-2019.pdf \(bharatbiotech.com\)](https://www.bharatbiotech.com/press-release/2019/11/14/chirorab-re-launches-its-rabies-vaccine)

⁷⁹ While Bharat Biotech has received PQ for Rabipur, it is not clear whether this extends to Chirorab, the vaccine currently being produced by the company.

⁸⁰ *Chirorab Vaccine*, TATA 1MG, https://www.1mg.com/drugs/chirorab-vaccine-611728?srltid=AfmBOopTaCZqejr6btQCR5bIW16b7b5Qv_bwpavily2d1pTUcjD4hqeH&wpsrc=Google+Organic+Search (last visited Sept. 10, 2024).

⁸¹ *Measles, Mumps and Rubella Vaccine, Live, Attenuated*, WHO, <https://extranet.who.int/prequal/vaccines/p/measles-mumps-and-rubella-vaccine-live-attenuated-2>; *Measles, Mumps and Rubella Vaccine, Live, Attenuated Package Insert*, https://extranet.who.int/prequal/sites/default/files/vwa_vaccine/pq_142_143_144_145_MMR_SIIPL_PI_UNI_CEF-2022.pdf (“The mumps virus is grown on chick fibroblasts from SPF eggs.”).

⁸² *Measles, mumps and rubella vaccine (MMR) price data*, UNICEF, <https://www.unicef.org/supply/media/20206/file/MMR-vaccine-prices-06122023.pdf>

⁸³ *VaxiRab N*, WHO, <https://extranet.who.int/prequal/vaccines/p/vaxirab-n>; *VaxiRab N Package Insert*, https://extranet.who.int/prequal/sites/default/files/vwa_vaccine/FVP-P-330_Rabies_1dose_Zydus-PI-2024_0.pdf (“Virus is propagated in chick embryo fibroblast cell culture and Inactivated by β -propiolactone.”).

⁸⁴ *Vaxirab N 2.5IU Injection*, TATA 1MG, https://www.1mg.com/drugs/vaxirab-n-2.5iu-injection-232000?srltid=AfmBOopLdY_ft8mFSVimIjZngzEU-99pkUTUpmiQPqeXQ02c8rDXnAW&wpsrc=Google+Organic+Search (last visited Sept. 10, 2024).

⁸⁵ *Measles vaccine*, WHO, <https://extranet.who.int/prequal/vaccines/p/measles-vaccine>; *Measles vaccine Package Insert*, https://extranet.who.int/prequal/sites/default/files/vwa_vaccine/pq_18_19_Measles_BioFarma-PI-2021.pdf (“Each dose of 0.5 ml contains not less than 1,000 CCID50 (cell culture infective doses 50%) of Measles virus strain CAM 70, prepared in SPF chicken embryo.”).

⁸⁶ *Measles vaccine price data*, UNICEF, <https://www.unicef.org/supply/media/20201/file/Measles-vaccine-prices-14062024.pdf> (last visited Sept. 24, 2024).

Manufacturer	Location	CEF-Based Product	FDA Approval or WHO PQ	Public Prices
Pfizer	Ireland	Tick-borne encephalitis virus used in vaccine ⁸⁷	Y	\$285 (Dept. of Veterans Affairs for TicoVac Jr.) ⁸⁸
Merck	U.S.	Measles and mumps virus used in MMR vaccine (rHA M-M-R II) ⁸⁹	Y	\$62.70 (Adult) \$25.68 (Child) (CDC) ⁹⁰

The above analysis is not exhaustive. While the manufacturers listed above may be well-equipped to receive technology transfer to produce MVA-BN drug substance, there may also be manufacturers not captured here that meet specifications that enable them to receive technology and know-how to complete the final step of the manufacturing process, called fill-and-finish. For example, Bavarian Nordic will reportedly assist one African manufacturer to fill-and-finish the MVA-BN vaccine on the continent.⁹¹ The selected manufacturer has not been disclosed. Separately, South African drugmaker Aspen Pharmacare stated that it was in talks with partners to manufacture mpox vaccines at its facilities, though it did not specify the vaccine.⁹²

While Bavarian Nordic has signaled its willingness to partner with a fill-finish manufacturer in Africa, the terms of such an agreement remain unclear. The U.S. government, along with other stakeholders, can urge Bavarian Nordic to share know-how, provide licenses and work with manufacturers in LMICs to help shore up mpox vaccine production for LMIC markets. If Bavarian Nordic cannot meet demand or fails to

⁸⁷ TICOVAC-tick-borne encephalitis vaccine injection, Pfizer, Inc., <https://labeling.pfizer.com/showlabeling.aspx?id=15600> (“TICOVAC is prepared from tick-borne encephalitis (TBE) virus propagated in chick embryo fibroblast (CEF) cells.”).

⁸⁸ Office of Procurement, Acquisition and Logistics (OPAL), U.S. DEP’T OF VETERANS AFF., <https://www.va.gov/opal/nac/fss/pharmprices.asp> (last visited Sept. 23, 2024).

⁸⁹ rHA M-M-R II, WHO, <https://extranet.who.int/prequal/vaccines/p/rha-m-m-r-ii>; M-M-R II Package Insert, <https://www.fda.gov/media/75191/download> (“M-M-R II vaccine is a sterile lyophilized preparation of (1) Measles Virus Vaccine Live, an attenuated line of measles virus, derived from Enders’ attenuated Edmonston strain and propagated in chick embryo cell culture; (2) Mumps Virus Vaccine Live, the Jeryl Lynn™ (B level) strain of mumps virus propagated in chick embryo cell culture;”).

⁹⁰ Current CDC Vaccine Price List, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/vaccines-for-children/php/awardees/current-cdc-vaccine-price-list.html> (last visited Sept. 20, 2024).

⁹¹ Mpox Response Plan Envisions Support Across 22 Countries, AFRICA CTRS. FOR DISEASE CONTROL & PREVENTION (Sept. 10, 2024), <https://africacdc.org/news-item/mpox-response-plan-envisions-support-across-22-countries/> (“Other efforts to contain the outbreak included an agreement with the European pharmaceutical company Bavarian Nordic to assist one of nine large African pharmaceutical companies to manufacture the Mpox vaccine.”); *Can the World Outmanoeuvre Mpox?*, EURACTIV (Aug. 29, 2024), <https://www.euractiv.com/section/health-consumers/news/can-the-world-out-manoeuvre-mpox/> (“Talks have started with Bavarian Nordic to establish a ‘fill and finish’ facility in Africa.”).

⁹² Nqobile Dlodla, *African Drugmaker Aspen in Talks to Manufacture Mpox Vaccines*, REUTERS (Sept. 3, 2024), <https://www.reuters.com/business/healthcare-pharmaceuticals/african-drugmaker-aspen-advanced-talks-manufacture-mpox-vaccines-2024-09-03/>

adequately pursue technology transfer, governments should take necessary action to prevent a future global health crisis.

For example, the Danish government should consider options to compel the company to share its knowledge with other vaccine suppliers. Danish law includes emergency preparedness authorities which may allow the government to direct private businesses like Bavarian Nordic to take special measures.⁹³ The Danish government could use this power to direct Bavarian Nordic to transfer technology in order to meet demand for the ongoing mpox emergency. It appears that the Danish Emergency Management Agency (DEMA) could serve a coordinating function between Bavarian Nordic, Danish health agencies, the WHO, the Africa CDC, and local vaccine manufacturers to effectuate such technology transfer. Currently, DEMA and the WHO have a standby partnership agreement, and in the past, they coordinated to respond to the Ebola outbreak in West Africa.⁹⁴

The Danish government also has the power to control and increase the supply of medicines to maintain domestic supplies, which could be triggered if Bavarian Nordic is unable to adequately meet demand for the ongoing emergency in LMICs while addressing domestic needs.⁹⁵

In the U.S., BARDA should include conditions for diversifying supply in any further support or purchase agreements with Bavarian Nordic, as essential to health security. The U.S. increasingly recognizes the role that public funding conditions can play in facilitating affordability and access. For example, ASPR includes contract conditions for fair pricing of health security-related medical products in the U.S.⁹⁶ and the NIH recently proposed a policy to require licensees to outline plans to promote access to products derived from taxpayer-funded inventions.⁹⁷

⁹³ Lov nr. 314 af 03.04.2017 om beredskabsloven, § 28(2).

⁹⁴ *Strengthening WHO's Disaster Response: DEMA and WHO Extend the Partnership Agreement for 5 More Years*, WHO, <https://www.who.int/news/item/11-10-2023-strengthening-who-s-disaster-response--dema-and-who-extend-the-partnership-agreement-for-5-more-years> (last visited Sept. 23, 2024).

⁹⁵ Lov nr. 339 af 15.03.2023 om lægemidler, § 76.

⁹⁶ ASPR recently secured a fair pricing agreement in its contract with Moderna to develop a pandemic flu vaccine. This followed the earlier announcement that ASPR was making fair pricing a standard part of development and procurement contract negotiations. News Release, U.S. Dep't Health & Hum. Servs., HHS Provides \$176 Million to Develop Pandemic Influenza mRNA-based Vaccine (July 2, 2024), <https://www.hhs.gov/about/news/2024/07/02/hhs-provides-176-million-develop-pandemic-influenza-mrna-based-vaccine.html>; The White House, *FACT SHEET: Biden-Harris Administration Announces Dozens of Pharma Companies Raised Prices Faster than Inflation, Triggering Medicare Rebates* (Dec. 14, 2023), <https://www.whitehouse.gov/briefing-room/statements-releases/2023/12/14/fact-sheet-biden-harris-administration-announces-dozens-of-pharma-companies-raised-prices-faster-than-inflation-triggering-medicare-rebates/>

⁹⁷ Request for Information on Draft NIH Intramural Research Program Policy: Promoting Equity Through Access Planning, 89 Fed. Reg. 45003 (May 22, 2024), <https://www.federalregister.gov/documents/2024/05/22/2024-11188/national-institutes-of-health-nih-office-of-science-policy-osp-request-for-information-on-draft-nih>

Bavarian Nordic will continue to secure financial gains through its business with high-income countries, so there is no plausible reason the company should hamper efforts to enable local production and diversified supply on the African continent. Corporate desire to maintain monopoly control over a publicly supported vaccine should not override the necessity to protect global health security. BARDA can play an instrumental role in conditioning future support to the company on the achievement of health security imperatives, which include global access to help stop outbreaks where they start. Moreover, the federal government may also consider exercising authorities under the Defense Production Act to compel knowledge sharing from the facility in the United States involved in fill-and-finish of the vaccine if that can support regional manufacturers abroad.⁹⁸

⁹⁸ Zain Rizvi, Jishian Ravinthiran, & Amy Kapczynski, *Sharing the Knowledge: How President Joe Biden Can Use The Defense Production Act to End the Pandemic Worldwide*, HEALTH AFF. FOREFRONT (Aug. 6, 2021), <https://www.healthaffairs.org/content/forefront/sharing-knowledge-president-joe-biden-can-use-defense-production-act-end-pandemic>

A More Equitable Mpox Response

The ongoing mpox emergency demands that Bavarian Nordic adopt a drastically different approach than it has in the past—one that is more public health-oriented and contributes to a coordinated global response. While there may be other policy and legal tools to expand local production of the mpox vaccine in LMICs, at the very least, the U.S. and Danish governments' long-term investments and stakes in MVA-BN provide leverage and cause to ensure that the company supports affordable and equitable access to its vaccine. Similarly, both governments, as well as Gavi and UNICEF, should push Bavarian Nordic to make clear commitments to transparency, affordability, and sharing technology and know-how with manufacturers in developing countries. This can help bring MVA-BN to the places it is needed most.