

**Tracking and Analyzing
Medical Countermeasures
for Emerging Health
Challenges: Mpox**

Issue 1: 25 October 2024

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Latest Mpox Response Insights

Less than 30% of needed vaccine doses have been pledged, even fewer delivered:

The Africa CDC/WHO Mpox Continental Preparedness and Response Plan for Africa aims to vaccinate 10 million people in the next 6 months, and it is estimated 18-22 million vaccine doses will be needed to achieve this. Currently, fewer than 5.4 million doses have been pledged for donation, UNICEF has agreed to purchase up to 1 million doses, and fewer than 300,000 doses have been delivered. Bavarian Nordic, the manufacturer of the MVA-BN vaccine, estimates it can supply 2 million doses by the end of 2024. This leaves a gap of approximately 10-14 million doses needed to reach vaccination targets. To close this gap, donations from high-income countries with national stockpiles will be critical.

Latest updates at a glance:

- Germany has reported their first case of clade 1b mpox, marking the second case of clade 1b in Europe. Sweden was the first country in Europe to report a case of clade 1b.
- Ghana, Zambia, and Zimbabwe have reported their first cases of mpox (no clade specified), further highlighting spread of the disease which has reached all five regions of Africa.
- The WHO extended prequalification for Bavarian Nordic's mpox vaccine, MVA-BN, for use in adolescent children aged 12-17. MVA-BN remains the only mpox vaccine with WHO prequalification.
- The first diagnostic to receive emergency use listing by the WHO is the Alinity m MPXV assay, which uses PCR to deliver a result within 2 hours.
- There remains no available therapeutic with WHO approval.
- Vaccinations have started to be administered in Rwanda and the Democratic Republic of Congo (DRC), but the DRC has faced challenges with vaccine uptake. Nigeria, DRC, and Rwanda are the only countries to have received vaccines.
- The EU has pledged €20 million for implementation of the joint Africa CDC/WHO Mpox Continental Preparedness and Response plan.
- The U.S. has pledged to donate 1 million doses of vaccines to the international mpox response alongside at least \$500 million to support the response.
- The Pandemic Fund has fast-tracked US \$128.89 million to support 10 countries impacted by mpox.

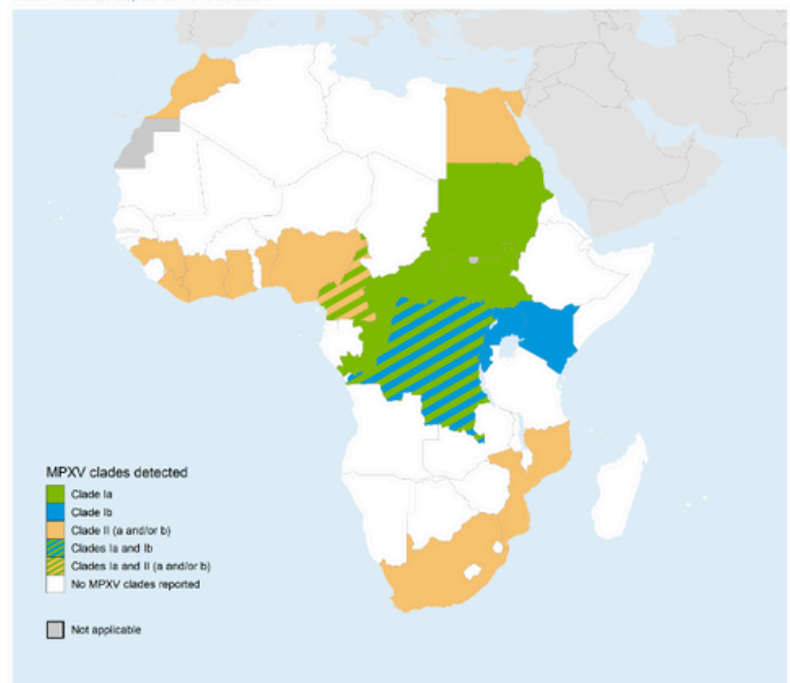
Introduction

The COVID-19 pandemic exposed significant global inequities in the access to therapeutics, vaccines, testing, and other medical interventions that could limit the range and impact of the disease. These global inequities are not limited to the COVID-19 pandemic and need to be critically addressed in the ongoing mpox outbreak. Through our QuickStart newsletter updates, we aim to serve as an external, independent source for tracking actions to meet commitments, catalyzing additional commitments to meet the need, and holding the world to account for the mpox response.

Epidemiology

On August 13th, 2024, the Africa CDC declared the mpox outbreak a Public Health Emergency of Continental Security (PHECS), which is the first time this designation has been used since the agency's inception. On August 14th, 2024, the World Health Organization declared the mpox outbreak a public health emergency of international concern (PHEIC). Mpox is an infectious disease that [causes symptoms](#) such as a painful rash, fever, muscle aches, and headaches. Symptoms [can last](#) 2-4 weeks, and the virus can be passed to others until all sores have healed and a new layer of skin has formed. Mpox [spreads](#) through close skin to skin contact with someone who has mpox, through contact with contaminated objects or needle injuries, during pregnancy or birth, or from exposure to an animal with mpox. Currently, the animal reservoir of mpox is unknown.

MPXV clades detected in Africa
 from 1 Jan 2022, as of 13 Oct 2024



The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Colours and shaded lines on maps represent approximate border lines for which there may not yet be full agreement.

Data Source: World Health Organization
 Map Producer: WHO Health Emergencies Programme
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Source: WHO 2022-2024 Mpox Outbreak: Global Trends

There are [two clades](#) of the virus: clade I (subclades Ia and Ib) and clade II (subclades IIa and IIb). Clade I is more likely to cause severe illness and death, and is currently spreading in

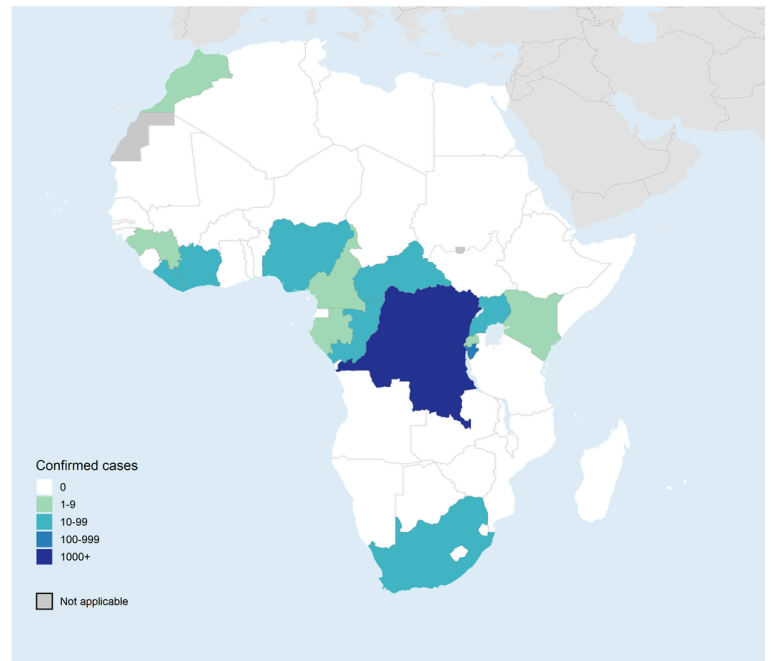
Central and Eastern Africa. Historically clade I mpox cases typically resulted from contact with an infected animal, but subclade Ib cases appears to be [spreading](#) mostly through human-to-human contact. Subclade Ib is a newer subclade and its spread from the Democratic Republic of Congo (DRC) to surrounding countries (Burundi, Kenya, Rwanda, Uganda) is partly what triggered the PHEIC declaration. Clade II was the cause of the 2022 outbreak and usually causes less severe illness, and is endemic to West Africa.

[In 2024 alone](#), through 21 October 2024, **there have been 42,442 suspected cases of mpox** from 18 African Union member states. Out of the suspected cases, 8,548 (20.14%) have been confirmed and 989 deaths (2.33%) were reported. In the last week, there were 1,052 new suspected cases, 435 of those cases were confirmed, and there was 1 death. In the Democratic Republic of Congo (DRC), the epicenter of the recent outbreak, **children accounted for 36.9% of all confirmed cases since September 27th**. The disease has spread to all 5 regions of Africa, and [Ghana](#), [Zambia](#), and [Zimbabwe](#) reported their first cases in October. On October 18th, **Germany reported their first case of clade Ib mpox**. Outside of the African region, Germany, Sweden, Pakistan, India, and Thailand are the only other nations with reported cases of clade Ib.

Regulatory

On September 13, the WHO granted [prequalification](#) to Bavarian Nordic's mpox vaccine (MVA-BN). This is **the first mpox vaccine to receive prequalification**. Two other mpox vaccines, ACAM2000 (Emergent BioSolutions) and LC16-KMB (KM Biologics)[GE1], are also under consideration. On October 8th, WHO [prequalification](#) for MVA-BN was **extended for use in adolescents** aged 12-17. Prequalification is often a prerequisite for organizations such as Gavi and UNICEF to begin procuring and distributing vaccines in LMICs. The Democratic Republic of Congo [granted](#) emergency use authorization in June for both MVA-BN and LC16-KMB vaccines. Nigeria has also [granted](#) emergency use authorization for the MVA-BN vaccine. On October 3rd, the [Alinity m mpox assay](#) was the **first in vitro diagnostic to receive emergency use listing** by the WHO. The [Alinity m mpox assay](#) is a PCR test that is able to provide a result in less than 2 hours. The Alinity m mpox assay is not considered a point of care or near of care PCR platform, but a lab-based diagnostic platform.

Confirmed mpox cases in 2024, Africa
from 01 Jan 2024, as of 15 Sep 2024



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Data Source: World Health Organization
Map Production: WHO Health Emergencies Programme
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Source: [WHO 2022-2024 Mpox Outbreak: Global Trends](#)

Vaccines

Supply:

The [estimated](#) need for vaccine doses is between **18-22 million doses** to meet the Africa CDC's goal of vaccinating at least 10 million people in 6 months. There are three existing vaccines that are effective against mpox: MVA-BN (Bavarian Nordic), ACAM2000 (Emergent BioSolutions), and LC16-KMB (KM Biologics), but at the present time the WHO recommends use of MVA-BN or LC16-KMB during an outbreak. Many doses of all three available vaccines are within high-income countries' national stockpiles, and **most countries have not disclosed the available quantity**. The U.S. [has over](#) 100 million doses of ACAM2000[GE2], and an unknown quantity of MVA-BN doses. It is unclear if the U.S. pledged doses for donation will come from the U.S. stockpile of vaccines. Canada [may have](#) up to 2 million doses of MVA-BN in the national stockpile. Japan [may have](#) up to 200 million doses of LC16-KMB, of which up to 3 million have been pledged. Spain [has pledged](#) 500,000 doses, which is around 20% of its stockpiles, while Germany [has pledged](#) 100,000 doses from its total military stockpile of 117,000 doses.

Manufacturing capacity:

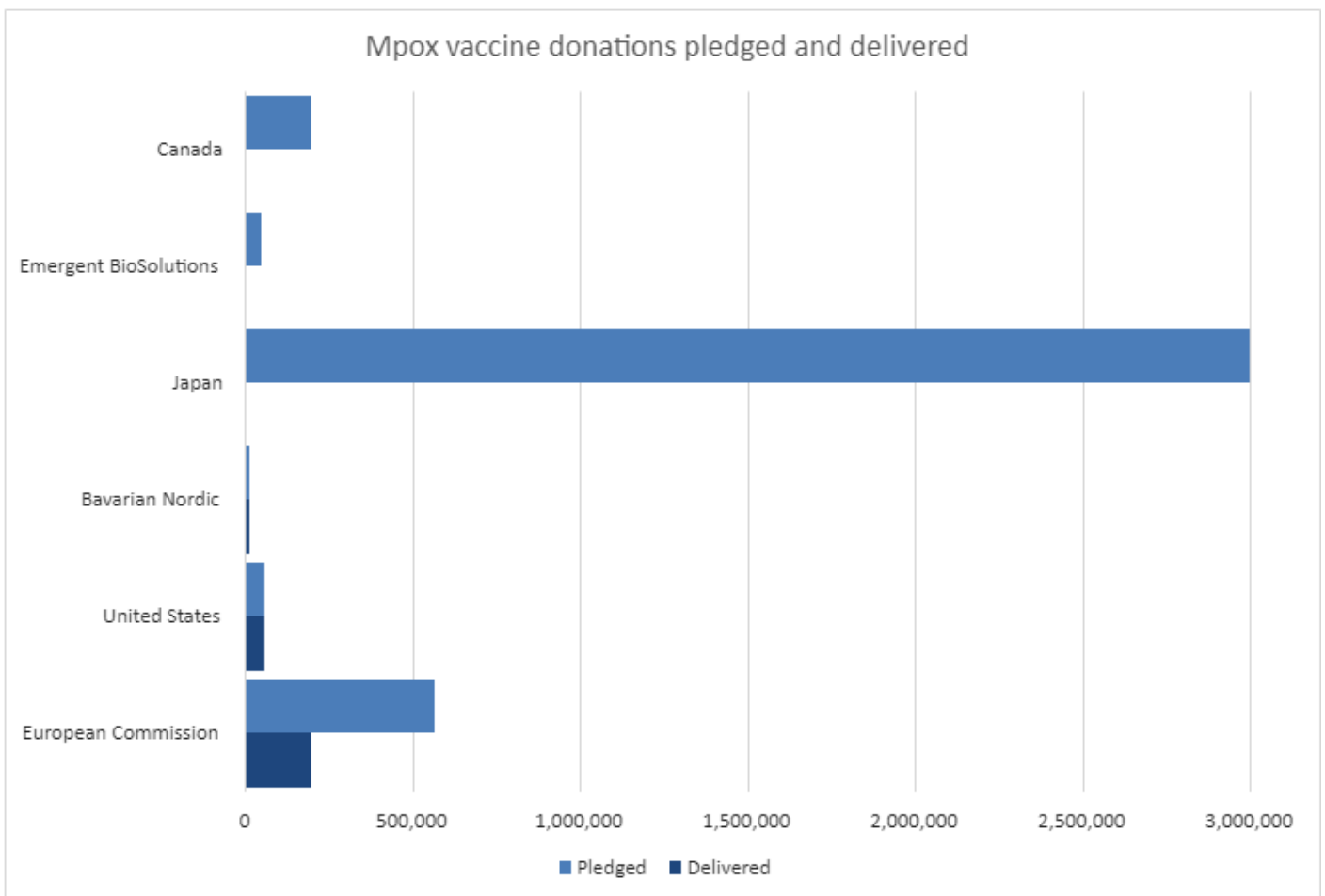
Bavarian Nordic, the manufacturer of the MVA-BN mpox vaccine, [estimates](#) it can supply **13 million doses of the vaccine by the end of 2025**, and is exploring options to expand capacity. By the end of 2024, the company estimates 2 million doses could be supplied. Based on early discussions to [transfer manufacturing](#) to other companies there is the potential for **an additional 50 million doses to be supplied in the next 12-18 months**. African vaccine manufacturers, Aspen Pharmacare and the Biovac Institute, have been in exploratory discussions with Bavarian Nordic about vaccine production. The potential for increasing manufacturing capacity is dependent on regulatory approvals and vaccine demand. With only 2 million doses that can be supplied by Bavarian Nordic by the end of 2024, **it will be critical for high-income countries with national stockpiles to donate doses** to meet the estimated need.

Procurement:

The European Health Emergency Response Authority [has negotiated](#) a joint contract to enable EU countries to access MVA-BN vaccines and tecovirimat for mpox. The exact cost of mpox vaccines is unclear, but it is estimated the [market price](#) of MVA-BN is around \$70-\$100 per dose, which would quickly deplete Gavi’s \$500 million First Response Fund. Gavi has [announced](#) plans to purchase 500,000 doses of MVA-BN, using money from the First Response Fund to procure the doses and support the transportation, delivery, and costs of administering the vaccines. UNICEF has [announced](#) an **agreement to purchase 1 million doses of MVA-BN**, which includes the 500,000 doses that were committed by Gavi. Bavarian Nordic has stated all **1 million doses will be made available for supply by the end of 2024**.

Donations:

Fewer than 5.4 million vaccine doses have [been pledged](#) for donation. On September 24th, the United States [announced](#) a **donation of 1 million doses of the MVA-BN vaccine to the international mpox response**. This marks the largest donation of MVA-BN mpox vaccines to date. This donation is in addition to the combined 60,000 doses the U.S. donated and delivered to Nigeria (10,000 doses) and the DRC (50,000 doses). The European Commission has pledged 566,500 doses. Canada has also [pledged](#) to donate up to 200,000 doses, stating that the number of doses delivered will be dependent on the receiving countries’ capacity for storage and administration. The available mpox vaccines have less strict cold-chain requirements compared to COVID-19 vaccines and many available mpox vaccines can be stored in a refrigerator (see table below). Japan [has pledged](#) up to 3 million doses of the LC16-KMB vaccine. Nigeria [donated](#) 1,000 doses of mpox vaccines (from the 10,000 doses they received from the U.S.) to Rwanda.



Source: Publicly available data compiled by the COVID QuickStart team

The WHO and partners have [established](#) an **access and allocation mechanism for mpox** medical countermeasures, including vaccines, treatments, and diagnostic tests. This mechanism was established as part of the interim Medical Countermeasures Network. The guiding principles for the mechanism are preventing illness and death, mitigating inequity, and ensuring transparency and flexibility.

Delivery and update:

A total of 280,880 vaccine doses have been delivered to 3 African countries. The majority of doses (265,460) were delivered to the DRC where it is estimated 3 million doses are required to end the mpox outbreaks. Nigeria has received 10,000 doses, and Rwanda has received 6,420 doses. Five countries have developed or are in the process of developing vaccination plans for mpox. **Both the Democratic Republic of Congo and Rwanda have begun vaccinating target populations**, while Nigeria is planning to roll-out vaccinations. Rwanda began [administering](#) mpox vaccinations to high-risk populations starting on September 17th. The DRC began [administering](#) vaccinations on October 5th, and has since **faced challenges with vaccine uptake** in part due to gaps in the awareness campaign. Health workers have recruited vaccinated persons who are trusted by the community to help promote benefits to receiving the mpox vaccine.

Cold-chain requirements for available vaccines:

MVA-BN	Shipped frozen (-20°C); can be stored frozen for long-term storage or refrigerated (2°C-8°C) and stored for 8 weeks.
LC16-KMB	Can be stored for 2 years in a refrigerator or for 4 weeks at room temperature (37°C or below).
ACAM2000	After reconstitution, can be stored in a refrigerator for 30 days. The antigen component is shipped frozen and can be stored frozen until expiry or refrigerated for up to 18 months or expiry. The diluent can be stored from 15°C-30°C.

Testing and therapeutics

[Testing capacity](#) for mpox in the Democratic Republic of Congo remains low due to limited access to laboratory testing in remote areas. It is [estimated](#) only **around 40% of suspected cases have been tested**. The DRC is [decentralizing laboratory services in an effort to improve diagnostic speed](#). There are no available antigen-based rapid diagnostic tests for mpox, so all mpox tests are conducted using PCR or near point-of-care PCR. The WHO is in the process of reviewing additional requests for diagnostic manufacturing approvals for mpox. The U.S. is [increasing](#) testing and surveillance for mpox, including through wastewater analysis, in response to the PHEIC. Kempegowda International Airport in India has [instituted](#) mandatory testing for mpox for international passengers.

There remains no therapeutic that has received WHO approval for mpox. Tecovirimat only has approval in the EU and US under animal rule and exceptional circumstances for mpox. [Proper use](#) of tecovirimat requires taking the medication within 30 minutes of eating a moderate or high fat meal for the full 14 day course of treatment. This may present difficulties for use in areas experiencing acute food insecurity such as the [Democratic Republic of Congo](#). Results of the [PALM007 trial](#) for tecovirimat in the Democratic Republic of Congo showed the antiviral drug was safe **but did not reduce the duration of mpox lesions in patients** with clade 1 mpox. The study largely included participants under the age of 18 and limited representation of persons living with HIV. Ongoing clinical trials aim to further understand why tecovirimat did not confer benefit, new approaches to treating mpox, and evaluating tecovirimat further in adults and people living with HIV infected with clade 2 mpox. Some monoclonal antibodies (mAbs) are in preclinical development, though it will be critical to consider the potential downstream accessibility of these candidates.

Therapeutics | 100 Days Mission mpox tracker

Day 60 of mpox PHEIC
13th October 2024 **IPPS**

Candidate Manufacturer	WHO-listed authority approved for mpox	WHO EUL	Use in under-18s	Ongoing trials ³	Availability	Manufacturing capability	Comments
Tecovirimat* Siga	✓ EMA†	✗	✗	6 ○ Ph I ② Ph II ④ Ph III ○ Ph IV	South Africa; used under EA-IND for mpox in USA	Easily manufactured at scale	Primary endpoint not met in PALM007 (Clade I in DRC) PK/PD and resistance results awaited
Brincidofovir Emergent BioSolutions	✗	✗	✗	0 ○ Ph I ○ Ph II ○ Ph III ○ Ph IV	Used under EIND for mpox in the USA	N/A	To be tested in the MOSA trial in DRC, Nigeria
VIGIV Emergent BioSolutions	✗	✗	✗	1 ① Ph II ○ Ph I ○ Ph III ○ Ph IV	N/A	N/A	Manufacturing/access at scale not currently feasible in LMICs
Cidofovir Gilead	✗	✗	✗	0 ○ Ph I ○ Ph II ○ Ph III ○ Ph IV	N/A	N/A	N/A

Novel antivirals: 3 novel antiviral candidates for mpox in preclinical development; **1 in early clinical development (ASCI0)**
Monoclonal antibodies (mAbs): 2 anti-mpox mAbs with ongoing preclinical studies [BFI 753 (Biofactura) and JEPO-CBRND (Just Evotec)]

KEY: Repurposed

* Available for compassionate use in South Africa and for clinical trials in the DRC and CAR or under application to MEURL, but no African country has applied for or completed an application to MEURL at this time.

† Approved under animal rule / exceptional circumstances

EIND: emergency investigational new drug
PK/PD: pharmacokinetics / pharmacodynamics
EA-IND: expanded access-investigational new drug
① Source: Pandemic PACT Programme

Source: [International Pandemic Preparedness Secretariat and Pandemic PACT Programme](#)

Financing

The [Mpox Continental Preparedness and Response Plan for Africa](#) requested an **estimated budget of nearly \$600 million USD**, of which around \$329 million (55%) will be allocated for mpox response across 14 countries and mpox readiness in 15 additional countries. The other nearly \$270 million (45%) has been earmarked for operational and technical support through partners. The budget included in the Africa CDC and WHO Mpox Continental Preparedness and Response Plan for Africa does not include costs associated vaccine procurement, which is dependent on price negotiations with manufacturers and donated doses.

New financial pledges:

Democratic Republic of Congo	\$10 million to support response efforts
African Union	\$10.4 million to support response efforts
European Union	€20 million towards implementation of the joint Africa CDC/WHO Mpox Continental Preparedness and Response Plan
United States	at least \$500 million to support response efforts to be delivered bilaterally and through multilateral institutions
Gavi	\$2.9 million from existing funds to support the DRC's vaccination efforts
Global Fund	\$9.5 million to support the DRC's response

Total estimated pledges for mpox response: USD \$554,400,000

[The Pandemic Fund](#) has decided, under the Fund's second call for proposals, **to fast-track US \$128.89 million to support 10 countries** in their response to mpox. This funding will go to projects that aim to enhance national and cross-border surveillance and early warning systems; strengthen laboratory capacities for disease detection, sequencing, and genomic surveillance; build a skilled workforce equipped to detect and rapidly respond to health threats and emergencies; and foster multisectoral coordination for pandemic prevention, preparedness, and response through a One Health approach. The 10 countries are: the DRC, Burundi, Rwanda, Uganda, Kenya, Sudan, Djibouti, Ethiopia, Somalia, and South Sudan.

In the news

Mpox access and allocation mechanism: <https://www.who.int/initiatives/i-mcm-net>

WHO mpox testing guidance: <https://www.who.int/publications/i/item/WHO-MPX-Laboratory-2024.1>

Mpox vaccine generates robust response in adolescents: <https://www.nih.gov/news-events/news-releases/mpox-vaccine-safe-generates-robust-antibody-response-adolescents>

WHO approves first mpox diagnostic test: <https://www.who.int/news/item/03-10-2024-who-approves-first-mpox-diagnostic-test-for-emergency-use--boosting-global-access>

INTREPID Alliance releases antiviral landscape analysis: <https://www.intrepidalliance.org/antiviral-pipeline/>

Pandemic PACT mpox outbreak page: <https://www.pandemicpact.org/outbreaks/mpox>

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