

after there had been a sustained decline in global cases.

Mpox has been reported in the DRC for more than a decade, and the number of cases reported each year has increased steadily over that period. Last year, reported cases increased significantly, and already the number of cases reported so far this year has exceeded last year's total, with more than 15 600 cases and 537 deaths.

The emergence last year and rapid spread of a new virus strain in DRC, clade 1b, which appears to be spreading mainly through sexual networks, and its detection in countries neighbouring the DRC is especially concerning, and one of the main reasons for the declaration of the PHEIC.

In the past month, over 100 laboratory-confirmed cases of clade 1b have been reported in four countries neighbouring the DRC that have not reported mpox before: Burundi, Kenya, Rwanda and Uganda. Experts believe the true number of cases to be higher as a large proportion of clinically compatible cases have not been tested.

Several outbreaks of different clades of mpox have occurred in different countries, with different modes of transmission and different levels of risk.

The two vaccines currently in use for mpox are recommended by WHO's Strategic Advisory Group of Experts on Immunization, and are also approved by WHO-listed national regulatory authorities, as well as by individual countries including Nigeria and the DRC.

Last week, the Director-General triggered the process for Emergency Use Listing for mpox vaccines, which will accelerate vaccine access for lower-income countries which have not yet issued their own national regulatory approval. Emergency Use Listing also enables partners including Gavi and UNICEF to procure vaccines for distribution.

WHO is working with countries and vaccine manufacturers on potential vaccine donations, and coordinating with partners through the interim Medical Countermeasures Network to facilitate equitable access to vaccines, therapeutics, diagnostics and other tools.

WHO anticipates an immediate funding requirement of an initial US\$ 15 million to support surveillance, preparedness and response activities. A needs assessment is being undertaken across the three levels of the Organization.

To allow for an immediate scale up, WHO has released US\$ 1.45 million from the WHO Contingency Fund for Emergencies and may need to release more in the coming days. The Organization appeals to donors to fund the full extent of needs of the mpox response.

Available from: <https://www.who.int/news/item/14-08-2024-who-director-general-declares-mpox-outbreak-a-public-health-emergency-of-international-concern>

## WHO PREQUALIFIES THE FIRST SELF-TEST FOR HEPATITIS C VIRUS

**10 July 2024** - The World Health Organization (WHO) has prequalified the first hepatitis C virus (HCV) self-test which can provide a critical support in expanding access to testing and diagnosis, accelerating global efforts to eliminate hepatitis C.

The product, called OraQuick HCV self-test, manufactured by OraSure Technologies, is an extension of the pre-qualified, OraQuick® HCV Rapid Antibody Test which was initially prequalified by WHO in 2017 for professional

use. The self-test version, specifically designed for use by lay users, provides individuals with a single kit containing the components that are needed to perform the self-test.

WHO recommended HCV self-testing (HCVST) in 2021, to complement existing HCV testing services in countries. The recommendation was based on evidence demonstrating its ability to increase access to and uptake of services, particularly among people who may not otherwise test.

National-level HCVST implementation projects, largely supported by Unitaid, have shown high levels of acceptability and feasibility, as well as empowering people through personal choice, autonomy and access to stigma-free self-care services.

“Every day 3500 lives are lost to viral hepatitis. Of the 50 million people living with hepatitis C, only 36% had been diagnosed, and 20% have received curative treatment by the end of 2022,” says Dr Meg Doherty, WHO Director for the Department of Global HIV, Hepatitis and STI Programmes. “The addition of this product to the WHO prequalification list provides a safe and effective way to expand HCV testing and treatment services, ensuring more people receive the diagnoses and treatment they need, and ultimately contributing to the global goal of HCV elimination.”

WHO’s prequalification (PQ) programme for in vitro diagnostics (IVDs) evaluates a range of tests, including those used for the detection of antibodies to HCV. The programme assesses IVDs against quality, safety and performance standards. It is a cornerstone in supporting countries in achieving high-quality diagnosis and treatment monitoring.

“The availability of a WHO prequalified HCV self-test enables low- and middle-income countries have access to safe and affordable self-testing options which is essential to achieving the goal of 90% of all people with HCV to be diagnosed,” says Dr Rogério Gaspar, WHO Director for the Department of Regulation and Prequalification. “This achievement contributes to improving access to quality-assured health products for more people living in low-income countries.”

WHO will continue to assess additional HCV self-tests, support evidence-based implementation, and work with communities to expand available options to all countries.

Available from: <https://www.who.int/news/item/10-07-2024-who-prequalifies-the-first-self-test-for-hepatitis-c-virus>