

EBOLA

Fighting the outbreaks

EMA has worked together with regulatory authorities around the world to support WHO in combating outbreaks

Outbreaks

The first Ebola disease outbreaks were reported back in 1976. Since then more than 30 outbreaks have occurred in Africa (mostly in Sudan, Uganda, the Democratic Republic of Congo, and Gabon).

Currently, the Democratic Republic of Congo (DRC) is grappling with the world's second largest Ebola epidemic on record.

August — WHO declared Ebola outbreak in West Africa a public health emergency

First vaccine

Ervebo is a genetically engineered, replication-competent, viral vectored vaccine. Data from clinical trials and compassionate use programs have shown that Ervebo protects against Ebola virus disease in humans, following a single dose.

June — Ebola outbreak in West Africa ended

May — DRC Ebola outbreak started
July — DRC Ebola outbreak ended

May — DRC Ebola outbreak started
July — DRC Ebola outbreak ended
August — A second Ebola outbreak started in DRC

July — WHO declared Ebola outbreak in DRC a public health emergency

Vaccine approval

In October 2019, EMA's committee for human medicines adopted a positive opinion for granting a conditional marketing authorisation for Ervebo.

In November 2019, the European Commission (EC) adopted a decision on the EU-wide marketing authorisation of the vaccine—an important step on its path to patient access.

Our role

Ebola virus disease is a rare but severe illness caused by the Ebola virus. Death rates in infected patients have ranged from 25% to 90% in past outbreaks.

Since 2014, EMA has provided advice on the development, evaluation and approval of medicines to fight Ebola virus disease.

2014

- EMA ad-hoc expert group established
- Review of experimental Ebola treatments started
- Interim report on experimental treatments review

2015

- Clinical trials of **1st investigational vaccine** started

2016

- Final report on experimental treatments review
- Application for accelerated assessment of **1st investigational vaccine**
- PRIME eligibility for **1st investigational vaccine**

2017

2018

- EMA contributed to WHO consultations on monitored emergency use of unregistered and investigational interventions for Ebola virus disease
- EMA contributed to a WHO ad-hoc expert consultation on clinical trials for Ebola therapeutics

2019

- EMA contributed to WHO Ebola vaccine evaluation and therapeutics consultations
- Marketing authorisation application for **1st vaccine against Ebola**
- Approval for accelerated assessment of **2nd investigational vaccine**
- EMA supported the EC's Health Security Committee to promote availability of investigational therapeutics and vaccines in Member States
- Positive opinion for granting a conditional marketing authorisation for **1st vaccine against Ebola**
- **Marketing authorisation** for 1st vaccine against Ebola **granted** by the European Commission