## Interim recommendation Ebola vaccines

On 1 August 2018, the Ministry of Health of the Democratic Republic of the Congo declared a new outbreak of Ebola virus disease in North Kivu Province. The Ministry of Health, WHO and partners are responding to this event, and working to establish the full extent of this outbreak<sup>1</sup>.

This new outbreak of Ebola virus disease is affecting north eastern provinces of the Democratic Republic of the Congo, which border Uganda. The province of North Kivu is among the most populated provinces, with eight million inhabitants. It shares borders with four other provinces (Ituri, South Kivu, Maniema and Tshopo) as well as with Uganda and Rwanda. The subregion has been experiencing intense insecurity and worsening humanitarian crisis, with over one million internally displaced people and a continuous efflux of refugees to the neighboring countries, including Uganda, Burundi and Tanzania.

Therefore, potential risk factors for transmission of EVD at national and regional levels include the transport links between the affected areas, the rest of the country, and neighboring countries; the internal displacement of populations; and displacement of Congolese refugees to neighboring countries. The country is concurrently experiencing several epidemics and a long-term humanitarian crisis. Additionally, the security situation in North Kivu may hinder the implementation of response activities. Based on this context, the public health risk is considered high at the national and regional levels and low globally.

This context puts limitations to the implementation of the ring vaccination strategy based on the identification of contacts, as recommended by SAGE in April 2017<sup>2</sup>. Hence, there was a need to urgently review options for alternative strategies for the use of rVSVAG-ZEBOV-GP vaccine should ring vaccination strategy become unfeasible.

Given the urgency of the matter, the members Strategic Advisory Group of Experts (SAGE) Working Group on Ebola vaccines and the SAGE members have reviewed the epidemiological situation and the evidence available to the Working Group with regard to the different candidate Ebola vaccines and the impact of different interventions.

While ring vaccination remains the preferred strategy (as stated in the April 2017 SAGE report <sup>3</sup>), geographic targeted approach was proposed as an exceptional alternative if the ring vaccination around a laboratory confirmed case of Ebola proves unfeasible. The following interim recommendation was agreed upon:

"Should an Ebola disease outbreak occur before the candidate vaccine is licensed, SAGE recommended that the rVSVΔG-ZEBOV-GP vaccine be promptly deployed under the Expanded Access framework, with informed consent and in compliance with Good Clinical Practice. If the outbreak is caused by an Ebola virus species other than Zaire, consideration should be given to the use of other candidate vaccines that target the putative viral species.

Ring vaccination, as used in the Phase 3 study in Guinea, is the recommended delivery strategy. This should be adapted to the social and geographic conditions of the outbreak areas and include people at risk including but not limited to: (i) contacts and contacts of contacts; (ii) local and international health-care and front-line workers in the affected areas and (iii) health-care and front-line workers in areas at risk of expansion of the outbreak."

A geographically targeted vaccination strategy can be considered in settings where it is not possible to identify the individuals making up the ring vaccination cohorts because of serious security, social or epidemiological issues. In this case, the geographic area immediately around an Ebola case, such as a village or a neighborhood, is most likely to include those individuals who were the contacts or contacts-of-contacts of the index case.

An expanded strategy to vaccinate all individuals in this defined geographic area will require a larger number of vaccinations than would be used in a ring vaccination intervention in the same area. Even in this setting, informed consent and compliance with Good Clinical Practice will be required, but the intensity of follow up of vaccinated individuals will be determined by the context of the intervention.

In this geographically targeted approach, the intent remains to immunize those people most at risk of secondary spread from an identified Ebola case."

Further discussions, including on the available evidence and potential use of other Ebola vaccines, will take place at the forthcoming SAGE meeting in October 2018.

<sup>&</sup>lt;sup>1</sup> http://apps.who.int/iris/bitstream/handle/10665/273640/SITREP\_EVD\_DRC\_20180807-eng.pdf?ua=1

<sup>&</sup>lt;sup>2</sup> http://apps.who.int/iris/bitstream/handle/10665/255611/WER9222.pdf;jsessionid=84A8710145124E5C537187BEFD46D5DC?sequence=1

<sup>&</sup>lt;sup>3</sup> http://apps.who.int/iris/bitstream/handle/10665/255611/WER9222.pdf;jsessionid=84A8710145124E5C537187BEFD46D5DC?sequence=1