International Coordination Group on vaccine provision for Ebola virus disease

Report of the annual meeting

12 October 2021
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# Abbreviations and acronyms

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<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>EBOV</td>
<td>Ebola virus</td>
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<td>EVD</td>
<td>Ebola virus disease</td>
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<td>FDA</td>
<td>Food and Drug Administration (USA)</td>
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<td>ICG</td>
<td>International Coordinating Group</td>
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<td>SAGE</td>
<td>Strategic Advisory Group of Experts on Immunization</td>
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<td>UNICEF</td>
<td>United Nations Children’s Fund</td>
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<td>WHO</td>
<td>World Health Organization</td>
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1. Background

The International Coordinating Group

The International Coordinating Group (ICG) on vaccine provision was founded in 1997 after a large-scale epidemic of meningitis that resulted in over 20,000 deaths across Sahelian West Africa. It was intended as a mechanism to manage and coordinate emergency provision of vaccine supplies and antibiotics to countries during major outbreaks. After the establishment of the ICG for epidemic meningitis control, two other emergency vaccine stockpiles were created, for yellow fever in 2001 and for cholera in 2013.

Context of outbreaks of Ebola virus disease

Ebola virus disease (EVD) is caused by the Ebola virus (EBOV) from the Zaire ebolavirus species. During 2014–2016, the largest EVD outbreak to date occurred in West Africa, resulting in over 10,000 deaths, mainly in Guinea, Liberia, and Sierra Leone. Since 2017, one or more independent EVD outbreaks have occurred each year; during 2021 alone, there were two outbreaks in the Democratic Republic of the Congo (in Butembo health zone, North Kivu province on 7 February 2021\(^1\) and in Beni health zone, North Kivu province on 8 October 2021\(^{2,3}\)) and another in Guinea,\(^4\) in addition to a suspected case in Côte d’Ivoire that was later ruled out.\(^5\)

Available vaccines and recommendations of the Strategic Advisory Group of Experts on Immunization

Currently, two licensed vaccines are available to prevent EVD. The first, Erbevo® (rVSVΔG-ZEBOV-GP), manufactured by Merck Sharp & Dohme, is based on a vesicular stomatitis virus that was genetically modified to express a surface glycoprotein of the EBOV from the Zaire ebolavirus species.

Since 2018, the WHO Strategic Advisory Group of Experts (SAGE) on immunization has recommended use of Ervebo® vaccine in an EVD outbreak due to EBOV of the Zaire ebolavirus species. This vaccine has been prequalified by WHO6 and has been recommended for inclusion in the ICG emergency stockpile. The vaccine is recommended for use in EVD outbreaks caused by EBOV in a ring vaccination strategy. Contacts of a confirmed case of EVD, contacts of contacts and frontline workers should be offered the vaccine. In the context of an outbreak, everyone who fulfills the definition of a contact of an EVD patient or a contact of contacts should receive a dose of the vaccine if they have not received the Ervebo® vaccine during the preceding six months.

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SAGE also recommends off-label use of Ervebo® vaccine in EVD outbreaks for children from birth to 17 years of age, as well as for pregnant and lactating women.

The second product, Zabdeno® and Mvabea®, which has also been prequalified by WHO7 and is produced by Janssen, comprises two vaccines, Ad26.ZEBOV and MVA-BN-Filo, given 56 days apart. Since March 2021, the SAGE has recommended that these vaccines be offered to people at some but lower risk of EVD in the context of an outbreak, such as health workers and frontline workers in neighbouring areas and countries to which the outbreak may spread. SAGE does not currently recommend this two-dose regimen for outbreak response by ring vaccination where immediate protection is necessary, due to the 56-day delay between the two doses. In addition, SAGE encouraged countries at risk of EVD to further develop their capacity for rapid epidemic response and to form outbreak response teams and recommended a strategy of pre-emptively vaccinating national response teams with Ad26.ZEBOV and MVA-BN-Filo Ebola vaccines. SAGE also recommended the use of Ad26.ZEBOV and MVA-BN-Filo vaccines for international responders who regularly support EVD outbreak response efforts; laboratory workers with possible exposure to EBOV; those working in specialized research units handling EBOV; and those working in EVD treatment units who might treat EVD patients.

International Coordinating Group for Ebola virus disease

An ICG for EVD was initiated in September 2015 at the time of the major outbreaks in West Africa. Creation of an ICG for EVD was discussed in 2015 when effective vaccines suitable for emergency outbreak response became available. During the first meeting that year, representatives of WHO and ICG members and partners discussed preliminary criteria for approval of emergency requests for EVD vaccines, outlined the stockpiling mechanism, defined the content of the ICG emergency request form and decided to create the vaccine stockpile. The EVD vaccine stockpile, which currently consists of Erbevo® vaccines, was established on 1 January 2021. The stockpile is funded by Gavi, the Vaccine Alliance.

Annual meeting, 2021

The second annual meeting of the ICG for EVD took place on 12 October 2021. It was chaired by Dr Myriam Henkens of Médecins Sans Frontières, and participants included representatives from the WHO, UNICEF, Médecins Sans Frontières, the International Federation of Red Cross and Red Crescent Societies and Gavi (Annexes 1 and 2). The meeting took place after an expert technical consultation on EVD vaccines on 11 October 2021 with the manufacturers of Ervebo®, Zabdeno® and Mvabea® and EVD therapeutics.

The objectives of the meeting were to review the ICG stockpile and the mechanism for vaccine allocation and to discuss a report of the ICG Governance and Oversight Committee on the EVD vaccine stockpile; repurposing of expiring doses of stockpiled vaccines; use of EVD therapeutics in outbreaks at the same time as vaccination campaigns; and potential future inclusion of Zabdeno® and Mvabea® vaccines in the ICG stockpile.

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2. Findings of the Governance and Oversight Committee

Meeting participants summarized and discussed the findings of the ICG Governance and Oversight Committee meeting held on 6 October 2021, the week before the ICG meeting. The topics discussed included management of the ICG EVD vaccine stockpile and criteria for approval of emergency vaccine requests. Repurposing of vaccines nearing their expiration date was also discussed. The points raised by the Governance Oversight Committee meeting included the following:

- providing support to countries in effective ring vaccination in an outbreak and also training in contact tracing and ring vaccination, especially in countries at risk of EVD outbreaks (but without recent outbreaks) where health-care workers in immunization programmes have little experience of this vaccination strategy;
- preference for use of stockpiled EVD Ervebo® vaccine rather than investigational rVSVΔG-ZEBOV-GP. It was agreed that the ICG should decide which vaccine is to be used and to define exceptional situations in which use of investigational vaccines may be considered (e.g., when stocks of licensed doses are depleted) and the standard operating procedures for potential deployment of both vaccines;
- ensuring timely vaccine delivery in order to prevent further EBOV transmission and defining relevant target dates for arrival of vaccines in a country (The delay should be shorter than the seven days targeted for the other stockpiled vaccines.); and
- discussion of different options for reducing the delay to vaccine deployment; e.g., small initial shipments of EVD vaccines or pre-positioning stocks in high-risk countries while a full ICG request is prepared and approved.

3. The Ebola virus disease vaccine stockpile and vaccine supply, 2021

Since establishment of the ICG for Ebola, an agreement has been reached with Merck Sharp & Dohme supply division for provision of doses of Erbevo® for a rotating stockpile. As of October 2021, over 200 000 doses of Erbevo® were available in the ICG stockpile for use in EVD outbreak response. It is anticipated that, given current production plans, the ICG revolving vaccine stockpile of Erbevo® will increase to its targeted size of 500 000 doses over the period 2021–2025. The US Government has contracted Merck Sharp & Dohme to provide one million doses of Ervebo® during the same period. In addition to the Ervebo® stockpile, about 450 000 doses of investigational rVSVΔG-ZEBOV-GP are still available.

In the next two years, the number of doses in the stockpile is expected to increase to its targeted size. Because of limited vaccine availability and the unpredictable nature of EVD outbreaks, Merck Sharp & Dohme is currently committed to supply Ervebo® to the ICG stockpile as a priority to ensure rapid access for emergency response by any country facing an outbreak.

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8 Emergency stockpile availability report - Ebola vaccine | UNICEF Supply Division
4. Requests to the International Coordinating Group, decisions and deployment

Meeting participants discussed the criteria for release of vaccines from the EVD vaccine stockpile in response to emergency requests and the timeframes for shipping and deployment of vaccines after acceptance of requests.

The minimum criteria for approval of emergency vaccine requests were discussed and decided as:

- official declaration by a country of an EVD outbreak;
- confirmation of at least one EVD case caused by EBOV of the Zaire ebolavirus species as verified with GeneXpert® Ebola or an approved real-time polymerase chain reaction that detects filoviruses coupled with virus typing or sequencing, or confirmation by a regional reference laboratory if there is no national capacity;
- submission of the report of an investigation of the initial case or cases;
- submission of an ICG emergency vaccine request form providing information on the country’s capacity to conduct vaccination activities (including physical access and the security of areas targeted for ring vaccination campaigns), disease surveillance and contact tracing; and
- submission of a rapid risk assessment (as defined in the WHO Emergency Response Framework⁹) of the risk of potential spread, other outbreak control measures in place and local capacity to respond.

One of the guiding principles of ICG vaccine stockpiles is a rapid response in order to contain outbreaks. For the ICG Ebola, timeliness is even more critical, requiring more compressed timelines than for other ICG vaccine stockpiles. It was pointed out that, while a target of seven days for delivery of vaccines to requesting countries after receipt and approval of a full emergency vaccine request is sufficient for other ICG vaccine stockpiles, a target of 48 or 72 h should be considered more appropriate for EVD outbreaks.

It was suggested that more flexible procedures be in place to release limited initial doses of vaccine while a full request was being prepared (i.e., with the level of detail required for ICG vaccine stockpiles), before the ICG decision-making group began its evaluation, in order to improve the timeliness of the initial response. One approach could be to expedite vaccine delivery to countries in which at least one EVD case has been confirmed by pre-approving a small number (e.g., 1200) doses of Ervebo® vaccine before submission of a full emergency vaccine request. ICG members agreed that further discussions should be held in the coming months on the quantities of vaccines eligible for release from the stockpile before submission of a full request and on calculating the initial amount of vaccine necessary for starting ring vaccination operations.

It was proposed that, in addition to vaccines, small quantities of urgently needed therapeutics (e.g., 20–50 treatments) could be sent with the initial vaccine doses.

Another two options for expediting arrival of emergency vaccines in countries to respond to EVD outbreaks were discussed. The first would be to pre-position vaccines and therapeutics in some high-risk countries (e.g., Democratic Republic of the Congo) for rapid deployment to areas affected by outbreaks. A number of obstacles to this plan were noted, such as limited capacity in

some countries to maintain a functional, reliable ultra-cold chain for pre-positioned vaccines and therapeutics and a guarantee that the pre-positioned vaccines and therapeutics remain under the control of the ICG and are not used by the countries without submission of an emergency request. Other challenges to this option are rapid reallocation of pre-positioned vaccines and therapeutics for an outbreak in another country, obtaining export and import license and approvals from individual countries and coordination among countries.

The second option would be physical delivery to the outbreak location of a small number of vaccine doses and ultra-cold chain equipment (e.g., Artek™ vaccine storage devices) by a team from Geneva. The challenges inherent in this option include obtaining documentation and permission to transport EVD vaccines in air passenger luggage. The element of transfer of title of the vaccine and questions of product liability in such a situation make this option unfeasible.

With regard to use of vaccines in the field, while it was agreed that ring vaccination should be the preferred strategy, it was recognized that it might not be immediately feasible for a variety of reasons (including insecurity, limited access to populations affected by outbreaks and lack of surveillance or contract-tracing systems) and that strategies for use of EVD vaccines in the field might have to be adjusted according to the local context.

Meeting participants emphasized a “no-regrets” approach to decision-making, in which measures are adopted immediately, before all the dimensions and consequences of an emergency or outbreak are known, with the aim of saving as many lives as possible and interrupting transmission as soon as possible.

ICG members decided that specific criteria should be developed for the exceptional situations in which investigational vaccine doses can be used in emergency response and standard operating procedures for their allocation and use.

**Vaccine repurposing**

It was noted that the first doses of Ervebo® in the rotating ICG EVD vaccine stockpile will reach their expiration date in February 2023 and that action should therefore be taken to ensure their allocation for pre-emptive use, with sufficient lead time for vaccination campaigns, including activities such as community sensitization. The ICG members agreed to start discussions in the near future on repurposing stockpiled EVD vaccine doses approaching expiry for pre-emptive vaccination campaigns. It was nevertheless recognized that a decision on their allocation could not be reached during the 2021 meeting before clear recommendations were received from SAGE on use of Ervebo® outside of outbreaks. According to the SAGE secretariat, a position paper would become available during the first quarter of 2022.

Issues in repurposing EVD vaccines include defining the time before expiration at which repurposed vaccines could be released for use in pre-emptive campaigns, identification of target groups for vaccination and criteria for prioritization of vaccine allocation. The group agreed that further work is necessary to identify suitable health-care providers and frontline workers in high-risk areas as recipients of repurposed vaccines. They also agreed that, when SAGE has clarified the recommendation for pre-emptive use of EVD vaccines, a mechanism should be found for repurposing other ICG vaccine stockpiles approaching expiration.
Vaccine requests by partners outside areas at risk of outbreaks of Ebola virus disease

It was reported that requests have been made by Member States (Austria, France, Germany, United Kingdom) for small quantities of vaccine to vaccinate some frontline workers, including international responders, laboratory workers and personnel in EVD treatment units who may be at risk of transmission of EBOV from repatriated EVD patients. Meeting participants noted that, although provision of vaccine to these groups is outside the scope of the ICG, members could support extension of pre-emptive vaccination with Ervebo® to these groups. The ICG Secretariat noted that Zabdeno®/Mvabea® vaccines are also available on the market. The options discussed included vaccination of overseas responders in the field on arrival when deployed for EVD outbreak response and exploration of a potential agreement with the Hôpitaux Universitaires de Genève for vaccination with Ervebo® in Geneva. ICG members expressed a general preference for vaccination upon arrival in the field.

It was agreed as a general principle that, in light of the limited EVD vaccine supply, any allocation of vaccines to these groups should be minimized to prevent diversion of doses from EVD outbreak response. ICG members also agreed that the issue should be discussed later, once the stockpile reached the targeted 500,000 doses.

Zabdeno® and Mvabea® vaccine use during outbreak response and potential future inclusion in the stockpile

Meeting participants briefly discussed potential inclusion of Zabdeno® and Mvabea® vaccines in the ICG stockpile. The current recommendation is that these vaccines be offered to people at lower risk in areas to which an EVD outbreak might spread due to current uncertainty about how rapidly these vaccines confer full protection. This may pose challenges for approving requests, identifying target populations and planning campaigns. While these vaccines are not currently recommended for inclusion in the ICG stockpile, it was agreed that, if this recommendation was to change, further discussions should be held with SAGE to guide countries in use of these vaccines and to operationalize an emergency vaccine stockpile comprising both Ervebo® and Zabdeno® plus Mvabea®.

5. Therapeutics

Meeting participants recognized that providing EVD therapeutics in outbreak settings is critical to reduce mortality among EVD patients. In addition, use of therapeutics might increase the trust of families and communities in EVD vaccination campaigns and could increase support and demand for vaccination.

Ridgeback Biotherapeutics presented the results of a recent study in the development of Ansuvimab (Ebanga™), a monoclonal antibody therapy against Zaire EBOV, into a commercial product, with support from the US Government. The company obtained a license for Ansuvimab from the US National Institutes of Health in 2018 and has since attempted to make the product available for patients during EVD outbreaks, including in 2018–2020 in the provinces of North Kivu and Ituri in the Democratic Republic of the Congo as part of a clinical trial sponsored by the
US National Institutes of Health (the PALM trial\textsuperscript{10}). The US Food and Drug Administration (FDA) has approved Ansuvimab for treatment of people infected with Zaire EBOV.

Regeneron presented an update on their therapeutic product Inmazeb™, a cocktail of three monoclonal antibodies that inhibit EBOV surface glycoprotein. In October 2020, Inmazeb™, which was also evaluated in the PALM trial, was approved by the US FDA for treatment of EVD infections in adult and paediatric patients, including neonates born to mothers who are positive for EVD infection in real-time polymerase chain reaction.

Inmazeb™ and Ebanga™ are licensed therapeutics against Zaire ebolavirus species only.

Manufacturers posed questions to ICG members on licencing requirements for potential future inclusion of their products in the ICG stockpile. The importance of WHO prequalification of these therapeutic products was stressed, in particular when seeking customs and regulatory clearance for their entry and use in countries after approval of emergency requests. As both products are currently licenced by the US FDA, classified as requiring a stringent regulatory authority, they are eligible for abridged assessment for WHO prequalification. This can be obtained by submission of US FDA approval information, without submission of a full prequalification application dossier, on the basis that the product is the same as that approved by the US FDA (with some minor adaptations permitted for their use in low- and middle-income countries). It was agreed that ICG members and Ridgeback Biotherapeutics would continue discussions to support prequalification of Ansuvimab. Manufacturers were urged to understand individual countries’ post-marketing expectations for these products.

ICG members agreed that the EVD vaccine stockpile should include therapeutics to be deployed with vaccines after approval of emergency requests. Although the targeted size of the stockpile of therapeutics could not be confirmed during the ICG meeting, a minimum of 500 and a maximum of 2500 treatment courses of each product were suggested. The final stockpile size would depend on a number of factors, including product shelf life, production capacity and lead times and cost. The ICG recognized that standard operating procedures for decisions, approval of requests, deployment of therapeutic doses and strategies for procurement and financing would have to be developed in order for the EVD therapeutics stockpile to become a reality. As is the case for vaccines, rapid deployment of therapeutics in response to emerging EVD outbreaks will be essential to decrease mortality rates among cases.

ICG members agreed unanimously that the ICG for EVD should henceforth be referred to as “ICG Ebola” instead of the earlier proposal, “ICG Ebovax”. This decision reflects maintenance of an ICG stockpile of EVD therapeutics, in addition to vaccines.

6. Meeting decisions and action points

The action points noted and decisions taken with respect to the ICG EVD vaccine stockpile were as follows.

- It was agreed that the ICG Ebola is the mechanism for deciding whether to release investigational rVSVΔG-ZEBOV-GP or licensed Ervebo® vaccine. Priority should be given to use of the licensed vaccine rather than investigational vaccine.

- Consensus was reached on ensuring more flexibility in vaccine release in order to reduce the time to deployment of the vaccine to no more than 72 h. As vaccine deployment from the warehouse in Basel (Switzerland) takes more than 72 h, either small quantities could be advanced while a full request is being prepared or vaccines and therapeutics could be pre-positioned in high-risk countries such as the Democratic Republic of the Congo. WHO should also explore with the logistics unit whether a staff member could carry the vaccine in ARTEKs.

- ICG members decided that inclusion of Zabdeno® and Mvabea® vaccines in the stockpile would be premature, given the lack of clear guidelines of the role of the vaccines in outbreak response. The expert consultation held on 11 October 2021 listed questions on operationalizing the recommendations to be discussed with SAGE.

- Requests to access small quantities of Ervebo® vaccine should be considered in order to vaccinate international EVD responders on arrival in a country facing an outbreak. Local staff working with EBOV or in EVD treatment units could be vaccinated in Geneva.

- It was agreed that the ICG stockpile of EVD vaccine would also include doses of licensed therapeutics for treatment of patients with confirmed EVD. ICG members recognized that decisions on the characteristics of the stockpile and standard operating procedures for deployment of doses of therapeutics will be influenced by factors such as their price, shelf life and training required for their use.

- ICG members recommended discussions with SAGE as soon as possible on repurposing of stockpiled Ervebo® vaccine doses due to expire in February 2023 for use in pre-emptive vaccination campaigns. The WHO team on viral haemorrhagic fevers will contact the SAGE secretariat to discuss the questions raised by the expert group.

- WHO and partners should discuss the mechanism for prioritizing allocation of the doses remaining in the stockpile.

- The ICG will continue discussions with manufacturers of EVD therapeutics to support WHO prequalification of these products.

- The ICG members present agreed unanimously that the ICG for EVD should be referred to as “ICG Ebola” in future, instead of the earlier proposal of “ICG Ebavax”. This decision reflects inclusion of EVD therapeutics in the stockpile, in addition to vaccines.
# Annex 1. Meeting agenda

**Chair: Myriam Henkens**

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<thead>
<tr>
<th>Time</th>
<th>Topic</th>
<th>Presenter</th>
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<tr>
<td>13:15–14:30</td>
<td>Vaccines</td>
<td>WHO, Viral Haemorrhagic Fevers team</td>
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<td></td>
<td>• Criteria for vaccine release (one confirmed case)</td>
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<td></td>
<td>Time to start vaccination</td>
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<td>Vaccine shipment: 48–72 h, options: pre-positioning small stocks, advance shipment</td>
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<td>• Stockpile rotation, licensed Erbevo® vaccine batches to expire in 2023.</td>
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<td>o Preventive vaccination using these batches (healthcare and frontline workers)</td>
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<td>o Criteria for prioritization and risk analysis to decide on vaccine allocation</td>
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<td>o Is the ICG the mechanism for deciding on allocation of unused vaccine or remaining shelf life?</td>
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<td>• Criteria for releasing small quantities: Pre-emptive vaccination of healthcare and frontline workers to be deployed, laboratory technicians. Draft paper</td>
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<td>Role of Zabdeno® and Mvabea® vaccines during outbreak response (e.g., third ring)?</td>
<td>All</td>
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<td>Should Zabdeno® and Mvabea® be included in the ICG stockpile?</td>
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<td>Should we change the ICG name to “Ebovax” as we are planning to stockpile Ebanga® and Inmazeb® therapeutics?</td>
<td>All</td>
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<td>14:30–15:30</td>
<td>Treatments</td>
<td>Ridgeback, Sabue Mulangu Regeneron, Elizabeth Bradley</td>
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<td>Prequalification of Ebanga® and Inmazeb®, licensed monoclonal antibodies</td>
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<td>Investigational treatments in stock</td>
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<td>15:30–16:30</td>
<td>Discussion: Procurement of Ebanga® and Inmazeb®</td>
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<td>How many treatments? Funding, joint procurement</td>
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<td>WHO/Médecins Sans Frontières?</td>
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<td>Access to US national strategic stockpile</td>
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<td>16:30–18:00</td>
<td>Continued discussion on vaccines</td>
<td>Chair</td>
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<td>Conclusion and way forward</td>
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Annex 2. List of participants

ICG Ebola members
Myriam Henkens, International Medical Coordinator, Médecins Sans Frontières, Brussels, Belgium
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Malika Bouhenia, Technical Officer, EHI/HEI
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Matthias Stahl, Medical Officer, Prequalification Team (PQT)/Medicines Assessment (MED)
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