SUBJECT:	**EBOLA UPDATE**
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Section A: Overview

1. Purpose of the report

1.1 The purpose of this report is to provide the Board with:

(a) An update on progress in implementing the Board/EC decisions in response to the Ebola crisis as per the 4 key areas[1] identified in December 2014;

(b) An overview of the evolution of the current outbreak and the status of clinical development and procurement of candidate Ebola vaccines;

(c) Key strategic and programmatic questions emerging from the experience in the Ebola response.

2. Executive Summary

2.1 In the past 12 months the Alliance has worked at different levels (Headquarters, Regional and in-country) to implement the Board decisions. With the progressive reduction of the number of cases in the 3 affected countries - 2 of which have now been declared Ebola free - the focus of the international community has now shifted from control of the epidemic towards: (a) the recovery of the health and immunisation systems, (b) the creation of a stockpile for the response to future Ebola emergencies, and (c) lessons learned from the Ebola crisis and how they should inform improved preparedness and response to future outbreaks.

2.2 The activities in the three countries aimed at restoring routine immunisation and health systems have proceeded with varying degrees of intensity and

[1] Making an Ebola vaccine available, support deployment of the Ebola vaccine, support recovery of Health Systems and support recovery of Immunisation programmes in the three affected countries

results. Thanks to the implementation of several Supplementary Immunisation Activities in the first half of 2015, further outbreaks of vaccine preventable diseases have been prevented. Systematic interventions aimed at ensuring the recovery and strengthening of health systems have begun towards the end of 2015. Gavi financed activities have been tailored to the affected countries' limited absorptive capacity. WHO and UNICEF have played a key role in ensuring progress of these interventions.

2.3 The creation of a stockpile of an Ebola vaccine has also progressed. Following the publication of the interim results of the phase III trial of the leading vaccine candidate in August 2015, the Secretariat has quickly progressed in its negotiations with manufacturers to ensure the early availability of a sufficient number of doses of an Ebola vaccine, subject to successful WHO's Emergency Use Assessment and Listing (EUAL).

2.4 As a result of the waning epidemic and in the absence of an approved vaccine the Global Ebola Vaccine Implementation Team (GEVIT), a team that has been created under WHO leadership in order to facilitate the collaborative planning for the potential introduction of Ebola vaccines, has been refocused towards defining generic implementation plans that can be used in the case of future outbreaks.

2.5 In the wake of the Ebola outbreak, the international community has launched a number of initiatives to review lessons learned and identify means to enhance preparedness and response for to future epidemics. In this context, the Secretariat is proposing that the Board reflect on lessons from Gavi's engagement in Ebola and discuss what role the Alliance should play (and equally should not play) in preparing for and responding to future outbreaks at its Retreat in April 2016.

Section B: Content

3. Overview and update of Ebola budget

3.1 In December 2014 the Board approved the Ebola programme envelope of up to **US$ 390 million** to allow Gavi to contribute to the response to this outbreak, to prepare for possible future outbreaks and to enable the recovery of immunisation and health systems. The total amount approved under this envelope breaks down as follows:

(a) An amount of up to **US$ 300 million** was allocated to the production and procurement of up to 12 million courses of first-generation Ebola vaccines to be used for the current outbreak (2015-2016) and to create a global stockpile of first-generation vaccines for 2016-2020 to ensure preparedness

(b) An amount of up to **US$ 45 million** was allocated to fund an Ebola vaccine roll-out

(c) An amount of up to **US$ 45 million** was allocated to support the recovery of health and immunisation systems. Of these US$ 30.5 million were allocated to allow for a doubling of countries' HSS budgets, US$ 12.5 million to enable the restoration of routine immunisation programmes and US$ 2 million for waiving of co-financing for 2014-2015

3.2 To enable the above-mentioned vaccine and recovery efforts, an additional total of US$ 11.0 million has been approved through the Gavi business plan, out of which US$3.5 million was allocated to the Secretariat, US$ 7.0 million to WHO and UNICEF2 for additional headcount and consultants to provide support to countries, project management, policy and scientific engagement, monitoring and evaluation, legal and finance support. The remaining US$ 500k has been allocated to CSOs to enable their critical role in rebuilding confidence in the health systems.

3.3 Towards the total approved envelope of US$ 390 million, Gavi funding of US$ 100 million was made immediately available. Expenditure beyond that amount is dependent on additional funds being raised. The fundraising approach will be adapted to allow sufficient funding for the creation of a stockpile based on manufacturers' plans towards registration and prequalification. Outreach with regional development partners such as the African Development Bank and financiers will be continued to make sure stockpile financing can be secured when needed.

3.4 In the twelve months following the Board approval a number of activities have started leading to the following financial forecast and expenditures:

(a) Given the decline in number of cases and interrupted clinical trials, no fund has been currently disbursed for procurement of the Ebola vaccine and as a consequence no funds have been spent for deployment.

(b) A total of US$ 14.3 million have been used out of the US$ 45 million budget for recovery of health and immunisation systems:

- US$ 1.7 million have been agreed upon as co-financing waivers in the 3 countries.
- A total of US$ 12.6 million has been spent for recovery of immunisation programmes, split as follow: 2.4 million for Liberia (via UNICEF), US$ 6.1million for Guinea (via UNICEF) and US$ 4.1million for Sierra Leone (via UNICEF and WHO).
- No extra funds have been approved for doubling of countries HSS budgets since the countries still have to apply. However US$ 10.6 million have been allocated from re-programming of existing active HSS grants including US$ 2.6 million for operational costs for Measles SIAs.

[2] 2.5 million for 2015 and 1 million for 2016

(c) In 2015 the Gavi Secretariat has spent a total US$ 1.6m of which US$ 1.3 million for salary and staff costs and US$ 356k on professional services.

(d) The 2015 budget allocated to WHO and UNICEF for additional headcount and consultants has been fully disbursed for a total of US$ 5.0m.

(e) Finally, of the approved CSO budget, US$ 150k has currently been approved for Guinea and will soon be disbursed to CSO via Catholic Relief Services (CRS).

4. Evolution of the epidemic

4.1 Since the beginning of the outbreak there have been a total of 28.571 reported confirmed, probable, and suspected cases of Ebola virus disease (EVD) in Guinea, Liberia, and Sierra Leone up to 1 November, with 11.299 reported deaths (including over 500 deaths in health workers).

4.2 Over recent months, the epidemic has waned with only 62 cases occurring in Guinea over the last 14 consecutive weeks (last known case just released from hospital) while Liberia and Sierra Leone have been declared free of Ebola transmission. The Interagency Collaboration on Ebola [3] now concentrates on building on existing measures to drive case incidence to zero, and to ensure a sustained end to EVD transmission. This includes ensuring the existence of adequate country capacities to rapidly identify a reintroduction (either from an area of active transmission or from an animal reservoir) or re-emergence of virus from a survivor, as well as to enhance in country capacity for testing and counselling. Risks of undetected transmission are in fact still ongoing, as well as risks of transmission of Ebola virus from survivors through sexual transmission.

5. Impact of Ebola on health systems and routine immunisation

5.1 Beyond the unprecedented mortality, the Ebola epidemic had a devastating impact on health systems in the affected countries with disruptive effects on childhood immunisation. Liberia, Guinea and Sierra Leone's routine immunisation (RI) programmes, coverage levels and health systems have been severely affected by the Ebola outbreak. In all three countries, vaccine coverage had dropped by up to 50% (see table 1). This has resulted in several outbreaks of vaccine-preventable diseases and, as a consequence thereof, loss of confidence in the health care system. Outbreaks of measles, for example, have been reported in the first half of 2015 (primarily in Sierra Leone and Guinea). The closure of many health facilities and the loss of large numbers of health care workers (371 cases and 179 deaths in Liberia, for example) not only adversely affected routine immunisation but primary health care services in general.

[3] Interagency Collaboration on Ebola (OCHA, WHO and humanitarian partners) produces weekly situation reports on latest developments, epidemic status and ongoing efforts to get to and sustain zero cases

Country	DTP3 (% coverage) Jan 2014-June 2015	MCV1 (% coverage) Jan 2014-June 2015
Sierra Leone	81 – 46	69 -51
Guinea	85 -60	89- 63
Liberia	100 -51	95 -49

Table 1: Measles and DTP3 administrative coverage data

6. Overview of Gavi support for recovery efforts

6.1 Gavi's support to Ebola recovery has gone beyond a simple response to the Ebola epidemic to include a number of Supplementary Immunisation Activities:

(a) Effective implementation of catch-up and strengthening of vaccination campaigns (several DTP3, MCV1, Meningitis A, Measles and Polio campaigns conducted in 2015). As of Q2 2015, no further outbreaks of Vaccine Preventable Diseases (VPD) have been reported (Table 2)

	PIRI various Age (timing/ coverage)	Measles ORI/ SIA (timing/ coverage)	Polio SIA (timing/ coverage)	MenA (timing/ coverage)
Sierra Leone	Dec 2014 & Feb 2015	ORI: May/ June 2015 (97%)	May/ June 2015 (98.8%)	
Guinea		ORI: QI + April 2015 (10districts) National SIA: Nov 2015		August 2015 (95%)
Liberia		ORI: mid Oct 2015	April & May/ June 2015	

Table 2: Recent vaccination campaigns: dates and coverage rates (ORI: Outbreak Response Immunisation; PIRI: Periodic Intensification of Routine Immunization; SIA: Supplementary Immunisation Activity)

(b) Fast-track reprogramming of existing HSS grants to provide immediate access to funds for recovery activities

(c) Mitigation of people's loss of confidence in health care systems through engagement with CSOs in all three Ebola-affected countries and particularly in Guinea.

(d) Initiation of plans for the upgrade of supply chain.

6.2 Furthermore, Gavi has granted a waiver for the 2014 and 2015 co-financing requirements to Guinea, as part of its recovery plan. Liberia and Sierra

Leone have benefitted only from a 2015 co-financing waiver, having already fulfilled their 2014 co-financing obligations

6.3 To expedite national restoration efforts of the health and immunisation system, including catch-up vaccination campaigns, Gavi has applied flexibility in approving and disbursing necessary funds as decided by the Board. Modalities for disbursements have been worked out together with countries and tailored to their needs, financial management systems, and absorption capacity. Depending on financial agreements in place, funds have been disbursed through partners or through government systems, while care has been exerted that adequate reporting mechanisms are in place. This flexible and country-tailored approach has enabled the 3 Ebola-affected countries to not only catch up on the immunisation of children who missed their routine vaccines, but also to strengthen national efforts on routine immunisation programmes.

6.4 The doubling of HSS support approved by the Gavi Board will be most critical in 2016 and beyond when emergency funds begin to decrease. A tailored process for approving the affected countries' HSS grants through the IRC (Independent Review Committee) will be initiated before the end of 2015. The country plans are expected to include, where appropriate, reallocation of remaining HSS commitments in countries (approximately US$ 900k for Guinea, US$ 3.6 million for Sierra Leone and US$ 400k for Liberia). Due to systemic weakness of these countries' health systems, the implementation of EPI recovery plans requires major planning and monitoring efforts. As countries have just begun to implement prioritised activities related to EPI recovery plans, timings for the submission of HSS applications will need to be tailored to the absorption capacity of the countries. The countries are, therefore, not expected to apply prior to the end of 2016 (although allowed to apply as of January 2016). In the process of preparation of the upcoming HSS proposals special attention will be paid to ensure that the recovery efforts will be harmonised through additional support from WHO, UNICEF, B&M Gates Foundation, CDC, World Bank and CSOs. In particular collaboration efforts are continuing to ensure that Gavi's support complements World Bank and other resources that will be committed to national Health System Resilience Plans.

7. Outcomes achieved in Ebola-affected countries

The post-Ebola situation in Guinea

7.1 After the occurrence of 1.802 measles cases in Sept/ Oct 2014, several immunisation campaigns have been launched with UNICEF/ WHO support. Measles immunisation campaigns were conducted in Q1-Q2 2015 in several districts and a national measles SIA campaign (9-59 months) will be conducted in November 2015. The Meningitis A immunisation campaign has been successfully organized from 6 to 12 August and achieved a national coverage of 95% of the targeted population (from 1 to 29 years old) according to according to the post evaluation campaign conducted with the support of the technical partners.

7.2 Funds for the EPI recovery plan have been disbursed through UNICEF in the first week of August. The funds comprise a budget of US$ 6.1 million corresponding to the funds approved by the May HLRP to support the re-launch of the EPI system (this amount includes US$ 1.5 million for the recent Measles Supplementary Immunisation Activity). Additionally the last tranche of the current active HSS grant of US$ 502k which complements funding from the prior tranche still available in country (about US$ 400,000) was also disbursed through UNICEF.

7.3 A performance framework has been prepared with country stakeholders to monitor the achievement of the expected outputs stipulated in the Recovery Plan. The country has reported against the implementation early November; the SCM has judged the implementation of planned activities satisfactory.

7.4 The recruitment of Senior Technical assistance aimed to support the strategic orientations for the EPI recovery, was completed by UNICEF, jointly with the recruitment committee set in place with country stakeholders.

7.5 Supply chain equipment orders were initiated by UNICEF Supply Division and should be available in country by December 2015/ January 2016.

7.6 A proposal submitted by the Civil Society platform (Possav) has been reviewed and US$ 175,000 will be disbursed to the CSO for conducting community mobilization activities on immunisation and health issues pertaining to the post Ebola recovery plan. The disbursement will be performed via Catholic Relief Services (CRS) before end November 2015.

7.7 Finally, a Service Availability and Readiness Assessment study (SARA) has been initiated to assess the quality of service provision and to better inform the needs and gaps to be filled within the National health recovery plan. Gavi has co-funded this study (US$ 57k from the HSS funds available in country) together with the Global Fund (US$ 60k) and the CDC (US$ 4,5k).

The post-Ebola situation in Liberia

7.8 After 63 cases of measles cases occurred in Sept - Oct 2014, measles immunisation campaigns were conducted in response to the outbreak (ORI) in Q1-Q2 2015 in several districts including a national measles SIA campaign (99% coverage rate according to national administrative data[4]). Additionally, two rounds of integrated SIAs (measles with polio and Vitamin A) were conducted in May and June 2015 (including around 600,000 children and with coverage rates as high as 100% and 85%, respectively according to national administrative data[4]). A third round of integrated campaign (polio, Vitamin A and mebendazole) was conducted in mid-October 2015. Additional immunisation campaigns have been conducted across various antigens (1st and 2nd round of PIRI in Dec 2014 and Jan 2015, respectively). No major shortage in vaccine stock has been reported in the past months. The improved situation put the country in condition to

[4] It is worth noting that national admin data are not confirmed by survey therefore, especially for campaigns and even more in difficult settings, their quality and reliability can be low

plan for new vaccine introductions (HPV in Q4 2015, Rotavirus vaccine in March 2016 and IPV in July 2016).

7.9 Funds for the post-Ebola EPI recovery plan have been approved and disbursed. The funds comprise a budget of US$ 2.8 million, corresponding to the funds approved by the May HLRP to support the re-launch of the EPI system over 12 months. The approved funds have been channelled through UNICEF to manage potential fiduciary risks.

7.10 GAVI plans to disburse the 2 remaining tranches of the current active HSS grant in the coming months to allow the construction of two regional cold and dry stores. Since funds that were not utilised from the previous HSS grants are still available the original plan of development of a post-Ebola HSS proposal for Q3/4 2016 is now being revised.

7.11 An Effective Vaccine Management Assessment was conducted in August and the resulting Improvement Plan (i.e., improvement of cold chain/ supply chain) is near completion. The country is also developing a new cMYP (comprehensive Multi-Year Plan).

7.12 The proposal from CSOs from Liberia needed re-submission and hence, has been experiencing some delay. The EPI is assisting the secretariat to have the MOH review the proposal so that it can be endorsed in the next ICC meeting.

The post-Ebola situation in Sierra Leone

7.13 Integrated measles supplementary immunization activities were conducted in May and June 2015 with 1,344,409 children aged 9-59 months vaccinated (national vaccination coverage 88.15% according to national administrative data[5]). At the same time Oral Polio Vaccine was given to 98.8% of the target population. A second polio SIA was conducted in July 2015 (94.2% coverage) whereas a third round took place in October. Around 1.1 million children received Vitamin A and albendazole during the April round.

7.14 There was no shortage of vaccine for the campaign and for the time being Sierra Leone has sufficient stock of vaccines. The introduction of measles second dose is still planned for the end of November 2015 while IPV has to be further postponed due to supply constraints and is now scheduled to be introduced in July 2016. The Country is also working on preparing for the 2nd year of the HPV demonstration, which will require additional support as more than a one-year gap have incurred between the 1st and the 2nd year with the need to follow up the initial cohort.

7.15 Funds for the post-Ebola EPI recovery plan have been disbursed through UNICEF and WHO in September 2015. The funds comprise a budget of US$ 4.1 million (US$ 1.1 million for measles campaign transferred directly through UNICEF with the rest of the GAVI Early Recovery funding channelled through WHO and UNICEF).

[5] The overall quality of the health related data remains poor in Sierra Leone as indicated in the 2014 and 2015 Joint Appraisals and there was no independent evaluation of these coverage estimates

7.16 The Government is developing a new post-Ebola HSS proposal for submission in Q1 2016 with an approved ceiling of USD $ 12 million.

7.17 The establishment of a new funding mechanism (Integrated Health Project Administration Unit) for Gavi, Global Fund and World Bank cash support is a critical element that will be thoroughly reviewed to ensure alignment and complementarity with HSS funding from various other organisations and avoid duplication of funds.

7.18 The proposal submitted by the Civil Society Platform is still in the review process for additional clarification of the budget proposed by CRS.

8. Overall challenges encountered in Ebola-affected countries

Gavi's support to Ebola-affected countries faces several challenges. These include:

8.1 **Pre-existing weakness of the health systems**, in particular, limited health workforces in Ebola-affected countries have caused interruptions of and/or severely affected routine immunisation services. This challenge has been addressed by closely coordinating with partners and re-prioritising the workload of existing in country staff, by accelerating the recruitment of dedicated staff/consultants and by training healthcare workers. These measures have ensured that staff was available to take forward recovery efforts of routine immunisation and health services, including the training of further healthcare workers, that educational and social mobilisation messages were disseminated and that Ebola-related surveillance activities were managed.

8.2 A **significant drop (up to 50%) in DTP3 and MCV1 vaccine coverage rates** and several (limited) outbreaks of measles occurred in 2014 and 2015. The risk of leaving a substantial amount of children unvaccinated has been lowered by planning and conducting catch-up campaigns with multiple antigens, supporting programme management, strengthening logistics and ensuring adequate supply of vaccines and infection protection control equipment.

8.3 A major challenge has come from the **need for a high degree of alignment at country level among the different efforts** to ensure contemporary successful health system recovery, restoration of routine immunisation services and deployment of a future Ebola vaccine. While alignment is essential for the success of all recovery interventions and to avoid creation of an unnecessary additional burden on countries, timing of immunisation recovery may differ from the one of health systems. Development of specific immunisation recovery plans linked to the broader health recovery plan has proven essential to address this area of risk.

8.4 **Mistrust of the government** resulting in community concerns about re-engaging with health care systems posed an additional challenge to the success of EPI campaigns, the restoration of routine immunisation and the rebuilding of trust in health care systems. Particularly in Guinea, this

challenge has been addressed by UNICEF and WHO through a consolidated communication plan for strengthening social mobilisation and community outreach in collaboration with CSOs.

8.5 **Limited fund absorption capacity at country level** in view of scarce programme management capabilities. This challenge has been addressed by a prioritisation of the different recovery activities. The prioritisation will result in a staggered approach to disbursement of funds for recovery.

8.6 **Weak Government systems** have led to cash disbursements that carry **substantial financial risks** in the affected countries. In response to this challenge disbursements of cash have been carefully managed and differentiated approaches, adapted to the systems in place, have been set up such as disbursement through partners or common funding mechanisms such as in Sierra Leone. Frequent missions by Gavi's Senior Country Managers, close coordination with partners and other agencies on the ground and ongoing scrutiny of disbursement requests are further key measures to address this challenge.

9. Update on Ebola vaccines and clinical development

9.1 Because of the lack of Ebola cases, randomised controlled trials can no longer acquire meaningful efficacy data. As a result, 4 out of the 5 candidate vaccines that submitted an Expression of Interest (EOI) to UNICEF for procurement (see Section 10.1 for detailed explanation) are not being moved forward into phase III trials. Amongst these are those that completed phase II (Ad26/MVA Ebola vaccine) or completed phase I (lyophilised recombinant adenovirus Ebola vaccine and recombinant nanoparticle Ebola vaccine) or had to discontinue their phase III testing due to lack of Ebola cases in the region (e.g. ChAd3-ZEBOV vaccine tested in the phase II/III trial in Liberia was terminated ahead of schedule).

9.2 1 out of the 5 candidate vaccines (rVSV-ZEBOV vaccine) entered phase III clinical trials in Guinea and Sierra Leone. After the release of interim results from the phase III ring vaccination trials in Guinea revealed a high level of efficacy (100%, 95% CI 74.4-100%, p=0.0036) and no safety issues, the Data Safety and Monitoring Board for the examination of clinical trials recommended the discontinuation of randomisation and the immediate extension of candidate vaccine rVSV-ZEBOV to all people within the study region who were newly exposed to the Ebola virus (i.e., all identified contacts of so-called 'index' [6] cases). The recommendation followed approval from the Guinean ethics authorities. As a result of this and the availability of some clinical vaccine material, the phase III ring vaccination study was also initiated in Sierra Leone to enrol contacts of Ebola index cases.

9.3 Aside from the phase III ring vaccination trial in Guinea, there are two other phase III trials using candidate vaccine rVSV-ZEBOV. These trials target

[6] Index case is the initial patient in a target population for an epidemiological investigation. They are generally the first case of a condition or syndrome, whether or not the person has been affected.

population includes frontline and health care workers (in Guinea and Sierra Leone) and will only generate safety and immunogenicity data, as no cases of Ebola have occurred in these study populations.

9.4 While we are working to assure that vaccines will be available following approval according to EUAL (Emergency Use Authorisation and Listing Procedure) or formal regulatory review, ongoing clinical trials have been used to contribute to the control of the current epidemic.

9.5 According to SAGE recommendations, full deployment of an Ebola vaccine for mass vaccination and prophylactic use will require regulatory approval and hence, is not expected to occur before Q1 2017.

10. Update on vaccine procurement

10.1 Following the December 2014 Board decision, the implementation of the decision for procurement and production of Ebola vaccine and the creation of a vaccine stockpile initially focused on determining a structure that would allow Gavi to leverage its current model of procurement whilst adapting to the high level of uncertainty given the rapidly evolving situation that resulted in unknown demand levels for the vaccine. An Expression of Interest was issued by UNICEF, resulting in five manufacturers with candidate vaccines in Phase 1 expressing interest in supplying vaccine to UNICEF for procurement. Dialogue between the Gavi Secretariat and manufacturers ensued to ascertain the product characteristics and development status and timelines as well as to help determine what financing structures would work best for both Gavi and the manufacturers. No financial commitments were made at this stage. The rapidly declining epidemic and its consequent impact on the clinical development of candidate vaccines and their regulatory assessment also meant that it became impossible to envisage the procurement of a licensed vaccine for deployment or stockpiling in the near term. At the same time interim efficacy data for the candidate rVSV-ZEBOV vaccine was published, revealing a high level of efficacy and no safety issues

10.2 Given these developments, the focus of the work on production and procurement of vaccines shifted to ensuring the continued availability of a sufficient amount of courses of investigational vaccine, with stockpiling of licensed vaccine as the long-term solution. Therefore, a short-term and a long-term plan for ensuring availability of vaccine was proposed to the Executive Committee in September, which provides a financial incentive through an at risk pre-payment of an Advanced Purchase Commitment (APC) for a stockpile of licensed and WHO recommended vaccine. This pre-payment aims to ensure the manufacturer will both guarantee availability of investigational vaccine on an interim basis for any short-term outbreaks as well as continue to pursue full licensure for the vaccine. The Executive Committee approved Gavi entering into an APC for a licensed vaccine with one manufacturer. The agreement is currently being finalised. Details of the financial commitment to date will be shared with the Board during its closed session.

10.3 The Executive Committee was also supportive of the Secretariat pursuing discussions with other manufacturers regarding the possibility of an APC. Therefore, the Gavi Secretariat has also engaged other manufacturers to determine whether a similar financing structure should be made available to secure availability of other investigational vaccines that may be deployed in the short term in case of a new outbreak.

10.4 A stockpile of licensed vaccine aimed at ensuring long term preparedness should be created as soon as the first vaccine has been successfully licensed following full regulatory review and received WHO recommendation. Clear definition of the size of this stockpile based on WHO guidance and of the product characteristics can play a relevant role in incentivising manufacturers to continue their development efforts towards vaccines best suited for the intended use.

11. Update on preparation activities for Deployment of the Ebola vaccine

11.1 In the current situation where no licensed vaccine product exists that can be used outside of the clinical trial setting or for which use in an emergency has been authorised according to EUAL, the deployment of the vaccine for the ongoing outbreak continues under the oversight of the WHO team in charge of the clinical trials.

11.2 The Global Ebola Vaccine Implementation Team (GEVIT), which consists of global health agencies and Ebola affected countries, has developed operational plans, guidance documents and tools for different Ebola vaccination roll-out scenarios to be able to respond to future outbreaks once the vaccine is licensed and recommended. These plans target the at-risk population of health care and community workers as well as contacts of cases. The documents are designed to help immunisation programme managers and their partners to plan, organise, implement and evaluate Ebola Vaccine deployment activities including supply chain management. Gavi is part of the group, which is also focusing on other activities that are critical to vaccine roll-out, including social mobilisation and community engagement, and monitoring and evaluation.

11.3 In addition, modelling highlighted the importance of rapid deployment of vaccine in the outbreak setting to have optimal impact, which was integrated into the planning process. Plans for Ebola vaccine deployment have been fine-tuned with input from all Partners and countries at the recent Regional meeting organised by WHO (October 2015). Previous country visits to the three affected countries (6 visits in total) have been instrumental in evaluating challenges related to the cold chain and logistics and assessing opportunities for Community Engagement & Risk Communications to assure acceptability and trust of the new vaccine.

11.4 The current guidance document comprises a general plan for prevention of infection, vaccine deployment, a framework for country decision making on strategies to deploy vaccine. The guidance document also includes a plan for the cold chain which is based upon a “worst-case-scenario”, i.e. -80C storage and transport. As companies are working to improve vaccine

stability at higher temperature, the document provides for ample flexibility to accommodate temperature in case storage temperature of future vaccines is above -80C. The document further includes a framework for monitoring and evaluation of Ebola vaccine implementation. Besides guidance, the document also provides a list of tools and checklists for key implementers including EPI managers and community decision makers. A costing tool template for vaccine operational costs is currently being refined. The plan is very much based on lessons learnt during the clinical trials and from ongoing vaccination campaigns. The purpose of the plan is to ensure preparedness to a future Ebola outbreak.

11.5 The guidance document on Ebola deployment is scheduled to be finalised by the end of 2015. To achieve this some additional comments from countries are to be incorporated to ensure the needs are adapted to the country context.

11.6 In addition, partners together with the countries have made available a draft which outlines the deployment process for a potential future vaccination campaign. Several preparation activities are needed at the global/regional level as well as in-country to enable rapid vaccine deployment if an outbreak occurs. These activities may include:

(a) Organizing a global level hub ready to deploy cold chain equipment and supplies to the field

(b) Keeping an updated list of technical experts trained and ready to assist with vaccine deployment

(c) Identifying/establishing in country sites with secured power supply to run Ebola vaccine cold chain equipment

(d) Developing a strong in country cold chain management capacity

(e) Training of country staff to understand role of vaccine in Ebola outbreaks.

(f) Continuation of periodic KAP surveys conducted to stay informed on population perceptions of trial vaccine as well as acceptability and trust in a new Ebola vaccine.

(g) Within each country, the initiation of an all-partner exchange of ideas, planning and imminent action plans to build a national and regional communications response platform and strategy in the case of an outbreak.

11.7 In parallel, an Interagency Coordination Group is currently being defined. Building on the structure of the existing ICG for Yellow Fever and Meningitis a new mechanism will be put in place to guide the allocation of the available doses and, in case of multiple products available, to guide their selection. Given the technical nature of the decisions to be taken by ICG (e.g., assessment of relevance of outbreak, size of doses to be released, type of vaccine to be selected), the Gavi Secretariat will not be part of the ICG. It

has been agreed, however, that a timely and transparent reporting of decisions and rationale for those will be required to ensure consistency with Gavi's market shaping efforts.

12. Key reflections from the Ebola epidemic

12.1 In the wake of the Ebola outbreak, the international community has launched a number of initiatives to review lessons learned and identify means to enhance preparedness and response to future epidemics. These include, among others, the WHO's Independent Ebola Assessment Panel, the UN Secretary General's High Level Panel on Global Response to Health Crises, The Independent Panel on the Global Response to Ebola (Harvard Global Health Institute & London School of Hygiene and Tropical Medicine), the WHO Review Committee on the International Health Regulations, the Roadmap: Healthy Systems - Healthy Lives initiative launched by Germany and the WHO, and the Global Health Security Agenda facilitated by the Centers for Disease Control and Prevention (launched prior to Ebola outbreak). Based on the experience of the Ebola epidemic, these initiatives are reflecting on a number of key questions including:

(a) What capabilities are required to ensure rapid detection of outbreaks and real-time surveillance of their spread?

(b) What gaps are remaining for countries to meet their minimum obligations for reporting and responding to outbreaks, especially in the context of the International Health Regulations?

(c) What is the minimum capacity which every country's public health system needs in order to effectively respond to outbreaks and how can this be built?

(d) What should be the roles and responsibilities of key global organisations in contributing to and coordinating the global response to epidemics?

(e) How can we ensure that the necessary tools (e.g., vaccines, medicines, diagnostics) are available, or can be rapidly developed, to respond to outbreaks of infectious diseases (including by addressing market failures)?

(f) How can we ensure that the necessary financing is available and funding shortfalls do not delay outbreak response?

12.2 As the world reflects on these questions, it is timely for Gavi also to reflect on lessons learned from its part in the Ebola response and what role – if any – the Alliance should play in outbreak response and preparedness going forward. The Secretariat will work with partners and other experts to further refine our thinking on this and develop a framework for Board discussion at the April Retreat.