Ebola Vaccine Pre-tender Industry Consultation

18 September 2019
UNICEF Supply Division
Ebola vaccine: Programmatic background and context

- Outbreak DRC since August 2018, as of 27 August:
  - 2,997 cases of Ebola
  - 1,998 deaths
  - 893 survivors

- Investigational Ebola vaccine use to date:
  - ~ 200,000 doses
  - incl. health and frontline workers in Uganda, South Sudan, Rwanda and Burundi

- Vaccination strategy:
  - Reactive vaccination (reactive/emergency use)
  - Interrupt chains of virus transmission (Ring vaccination strategies)
  - Preventive vaccination (prophylactic use)
  - Frontline workers, healthcare workers, occupational risk due to profession

- SAGE recommendation (April 2019):
  
  SAGE WG recommended a stockpile size of 500,000 doses for outbreak response and some potential preventive vaccination of HCWs/FLWs at high risk of exposure, through a rotating stockpile
A stockpile of 500,000 doses has been recommended by SAGE based on work done jointly between WHO and Gavi, and discussed at SAGE WG.

6 demand scenarios were defined based on time and spread of outbreak, modelling work and WHO data, and likelihood.

A worst-case scenario based on the West Africa outbreak and ring vaccination strategy was defined (200K).

Two additional scenarios for targeted preventive vaccination of HCWs/FLWs were defined (additional 100K-200K doses).

Experience in Equateur & North Kivu, new modelling work & additional considerations informed final recommendations (500K).

First recommendations for stockpile size were made based on likely public health needs (100K doses recommended).

Further considerations on a worst-case scenario involving targeted geographical vaccination (>200K).

Work was presented and discussed with Ebola SAGE WG.

April 2018 — April 2019
Triggers for current tender

1. Secure supply of Ebola vaccine in support of SAGE recommendations for reactive vaccination and limited preventive vaccination (stockpile)

2. Initial vaccine candidates approaching WHO-PQ

3. Gavi funding envelope
   - Potential funding for 500,000 doses and their replenishment (to be confirmed Dec. 2019)
Ebola vaccine tender objectives

Tender objectives:

1. Secure access to quality assured vaccine(s) for **reactive** vaccination aligned with SAGE recommendations

2. Secure access to quality assured vaccine(s) for **preventive** vaccination aligned with SAGE recommendations (when available)

Clarification

Access may include supply of vaccines for:

1. Reactive vaccination as part of the interventions during an Ebola **outbreak**
   - Interrupt chain of transmission (e.g. by Ring vaccination)
2. Preventive vaccination as part of the interventions during an Ebola **outbreak**
   - Protect people at (high) risk (e.g. vaccination of health care workers, frontline workers)
3. Preventive vaccination as part of a preventive **program**
   - Protect people that may become exposed to risk of Ebola virus disease

Stockpile
Ebola vaccine tender objectives – intended outcomes

A. Secure access to quality assured (WHO PQ) **vaccines** for emergency/outbreak response (both reactive and preventative) by establishment of a rolling **stockpile** of **500,000 doses**.

B. Secure the maximum annual production capacity with the manufacturer(s) so that:
   i. the stockpile can reach the required level of 500,000 doses as soon as possible, and
   ii. sufficient production capacity is secured to replenish the stockpile at the preferred level considering the projected usage and vaccine expiry.
   iii. additional access to vaccines may be secured when the stockpile level is adjusted based on SAGE recommendations and/or guidance by the governing body/mechanism

C. Achieve maximum flexibility of use of vaccines in the stockpile to align with **SAGE recommendations**.
   i. the use of vaccine secured in the stockpile will be at the discretion of the governing body/mechanism responsible for the management of the stockpile.

D. Stockpiled vaccines are ready to be shipped to a country within agreed period (e.g. 3 working days) from receipt of UNICEF purchase order and confirmation from the recipient country.

E. The price per dose is in line with expectations: ‘Paying a price that reasonably covers manufacturers minimum requirements’, while acknowledging any investments by Gavi and/or other donors.

F. Enhance market intelligence of manufacturers with Ebola vaccines in development
Upcoming Ebola vaccine tender

**Duration:**
- 5-year tender (2020-2024)
- Tender duration may include option for extension (additional 2 years)

**Solicitation:**
- Request for proposals (RFP)
- Published on United Nations Global Marketplace ([www.ungm.org](http://www.ungm.org))
- Requirement for final acceptance of proposals
  - Application to UNGM for UNGM number
  - Simultaneous submission of most recent Audited Financial Statement and Quality System Certificate to the UNICEF Quality Assurance Supplier Evaluation Unit

- All suppliers/developers with an Ebola vaccine in their pipeline/portfolio will be invited to submit a proposal
  - UNICEF is seeking to achieve maximum flexibility to support program recommendations; encourage submission of proposals including those in development
  - Technical mandatory requirements will be established by WHO-PQ
  - UNICEF welcomes alternative proposals, including proposals which may include special contracting terms and being conditional upon firm UNICEF commitment to defined quantities, or subject to pre or advanced payments.
Upcoming Ebola vaccine tender

Questions that may be included in the tender:

1. What is the expected annual production capacity for your Ebola vaccine?
2. What is the capacity you are offering to UNICEF?
3. For manufacturers with a product in development the following information will be requested:
   a. Timelines for Phase I, II & III clinical trials
   b. When would the product expect to receive a national licensure from the country of production
   c. When would you expect to submit the product summary file (PSF) for WHO PQ
   d. When would you expect to have the product WHO PQ
   e. When would you expect to be able to offer UNICEF doses of the PQ product
4. Do you have a facility ready for production? If not, please provide the timelines for when you expect to have the facility ready?
5. What if the production time for the bulk?
6. What is the production time for the filling of the bulk, to having a product released both internally & by the NRA?
7. What is the shelf life of the bulk?
8. What is the expected shelf life of the finished product?
9. What will be the storage requirement with regard to cold chain of the finished product?
Upcoming Ebola vaccine tender (DRAFT) - timelines

- Tender issuance: 30 Sept.
- Bid by suppliers: 4 weeks
- Tender closure: 30 Oct.
- First awards finalization: Q1 2020

Additional awards:
- Initial awards will be made based on availability of vaccine to meet the mandatory requirements and tender objectives;
- If/when conditions change during the tender period, UNICEF will reach out to manufacturers that have submitted an initial proposal/offer to determine suitability of vaccines to meet programmatic requirements for additional awards.
Ebola vaccine tender: Questions for Industry

Tender timelines:
- The tender is expected to be issued September 30, with one month (4 weeks) for response. Will this be sufficient time for industry to respond?
- Timing of awards: Lead times for manufacturers to ensure supply (how many months in advance of supply availability)?

Tender duration:
- Does the duration (5 years with option for 2 year extension) provide sufficient visibility to appropriately plan production?

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THANK YOU!