Guidance on how to access the Oral Cholera Vaccine (OCV) from the ICG emergency stockpile

ICG
9/13/2013
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DESCRIPTION OF THE OCV EMERGENCY STOCKPILE

Recognizing the importance of cholera as a continuing public health problem, the World Health Assembly (WHA) adopted Resolution 64.15 in May 2011. This resolution calls for implementation of an integrated and comprehensive approach to cholera control, which may include the use of oral cholera vaccines (OCV).

In response to the WHA resolution, the World Health Organization (WHO), in consultation with technical partners, has established an OCV emergency stockpile that will be available principally for epidemic response. Vaccines for the stockpile will be purchased from WHO pre-qualified manufacturers only, at negotiated prices.

The stockpile is managed by The OCV International Coordinating Group (ICG) for vaccine provision which is composed of representatives from Médecins Sans Frontières (MSF), the International Federation of Red Cross and Red Crescent Societies (IFRC), the United Nations Children’s Fund (UNICEF), and the WHO. The OCV ICG Secretariat is hosted at WHO Headquarters in Geneva, Switzerland.

The role of the OCV ICG is to:

- Ensure the availability and rational distribution of emergency supplies of OCV vaccine to countries experiencing epidemics of cholera
- Ensure the rapid deployment of OCV in countries experiencing epidemics;
- Coordinate international efforts in preparing for, and responding to, epidemics of cholera.

MINIMUM REQUIREMENTS FOR ACCESSING VACCINE FROM THE STOCKPILE

- Reporting of a culture-confirmed cholera outbreak in any given area, with consideration for the number of specimens collected, type of strain, and laboratory capacity.
- Submission of a completed ICG request form (Microsoft Word document) and accompanying annexes (worksheets 1-5 in Microsoft Excel spreadsheet),
- Submission of a vaccination plan (content outline in annex 6) and a map of areas to be vaccinated and of adjacent areas.
- An OCV campaign has not been conducted in the previous 2 years in the same area (with consideration for the quality of implementation of the campaign, vaccination coverage, and population movement).
- The proposal to implement a reactive vaccination campaign has been reviewed and agreed by the National Health Authority.

APPLYING FOR OCV FROM THE EMERGENCY STOCKPILE

Send the completed OCV ICG request form and accompanying annexes with a map of areas to be vaccinated and adjacent areas, to the OCV-ICG Secretariat by email ICGsecretariat@who.int or outbreak@who.int or fax +41 22 791 4198.

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The OCV ICG decision regarding the release of vaccine from the ICG emergency stockpile is based on the information provided on the request form and in the supporting annexes. A request will not be accepted by the ICG until all components are complete. In order to reduce delays in processing, please ensure all documents are complete and there are no inconsistencies in the information provided.

If the ICG requires additional information to make a decision, the ICG Secretariat will contact the person who submitted the request. If that person is going to be unavailable in the days following the submission, please provide details of another person the ICG Secretariat can contact.

For assistance with filling out the request form and annexes, you may contact the WHO Country Office or WHO Regional Office (Inter Country Support Team).

A request for OCV may be made by any national or international organization or agency. In order to ensure the sustainability of its stock, the ICG requires the reimbursement of vaccines, shipment costs (including packing costs, insurance) and operational costs. The funds for reimbursement should be identified as soon as the ICG request has been submitted to the ICG.

**ICG PROCESS FOLLOWING SUBMISSION OF A REQUEST**

After the ICG request form and annexes are received by the ICG Secretariat, the following process will be initiated, provided the information is complete and there are no inconsistencies (Figure 1).

- The ICG Secretariat will circulate the complete request form and annexes to the OCV ICG partners (MSF, UNICEF, WHO, IFRC) for review and a decision within two working days.
- The decision will be communicated to the requesting country or agency, together with explanatory reasons if the request was not approved or partially approved.
- If the request is fully approved or partially approved by the ICG, the vaccine will be sent by aircraft for arrival in the country within 7 business days from the date the ICG approved the request.
- The shipment might be split up into smaller shipments, depending on its size and other variables such as cold chain capacity. The shipments will be consistent with the vaccination plan (e.g. for first and second doses).
- The Freight Forward agent, on behalf of the ICG Secretariat (WHO), will keep the requesting country or agency informed about the shipment volume and estimated date of arrival in the country.
ICG DECISION MAKING PROCESS
When an outbreak of cholera in a given area has been confirmed by the laboratory, the ICG will base its decision to release vaccine from the stockpile or not on:

1. The risk of extension of the outbreak
2. The capacity of the country to contain the outbreak
3. The feasibility of an immunization campaign
4. The availability of vaccines

There are a number of indicators that may be considered to estimate the potential impact of the vaccination campaign. Impact is based on the susceptibility of the population, the overall vulnerability of the population exposed, and the risk of spatial extension (refer to Annex A of this document).

ICG REQUEST FORM
To inform the decision making process as described in the previous section, the ICG requires the completed ICG request form and accompanying annexes, the vaccination plan and the map of areas to be vaccinated and adjacent areas.

The request form is comprised of 12 sections (A through L).

- Sections A through C contain information to determine the risk of extension of the outbreak.
Section D contains information to determine the capacity of the country to control the outbreak and
Section E and F pertain to the feasibility of implementing an OCV campaign.
Sections G and H provide detail on the vaccine licensed and available in the country
Sections I and J provides information on operational costs and reimbursement of funds to the ICG
Section K provides instructions on the completion of an additional form specifically related to Monitoring and evaluation
Section L allows request for logistical and technical assistance

Definitions of terms and other information to guide the completion of the request form are detailed below, by section.

### A. Epidemiological information

The information in this section of the request form is complemented by Annex 1 and 2 of the Excel spreadsheet. Annex 1 contains epidemiological data by place and week number (in the calendar year i.e 1-52) and will be used to assess the scale and progression of the epidemic. Please provide an epidemic curve if one is available.

Annex 2 (History of cholera) is used to assess the level of immunity in the population that may have been conferred by earlier exposure to cholera or by vaccination.

**Definition of terms:**

- **WHO case definition for cholera cases:**
  - **Suspect:** A case of cholera should be suspected when:
    - in an area where the disease is not known to be present, a patient aged 5 years or more develops severe dehydration or dies from acute watery diarrhoea;
    - in an area where there is a cholera epidemic, a patient aged 5 years or more develops acute watery diarrhoea, with or without vomiting.

  **Confirmed:** A case of cholera is confirmed when *Vibrio cholerae* O1 or O139 is isolated from any patient with diarrhoea.

  Once *Vibrio cholerae* has been confirmed, the WHO clinical case definition for suspect cases is sufficient to diagnose cases.

- **Cholera epidemic or outbreak:**
  An epidemic of cholera is said to have occurred when the incidence of cases is greater than expected (compared with the same period of time in previous years and in the same geographical area) in an area where cholera is endemic, or when there is a cholera case or a cluster of cases in a non-endemic area.

- **Endemic cholera:**
  Endemic cholera has been defined as the occurrence of faecal culture-confirmed cholera diarrhoea in a population in at least 3 of the past 5 years.
- **Seasonality of cholera:**
  Cholera may follow seasonal patterns. Seasonal situations that might increase transmission are drought, floods, rainy season. Historical data will be especially useful in determining thresholds of incidence and when and where outbreaks are most likely to occur.

  Time at which first cases were notified during the epidemic season will also determine the risk of spatial extension.

### B. Laboratory information

The information in this section of the request form is complemented by Annex 3 of the Excel spreadsheet.

- Cholera is confirmed by the presence of *V. cholera* in stools (stool culture). **The ICG will deploy vaccine only upon confirmation of an outbreak by culture** as this is the most reliable method of identification of *V. cholera*.
- RDTs are not sufficient as a test to trigger a vaccination response from the ICG and should always be complemented by culture results.
- All data fields in Annex 3 of the spreadsheet should be completed, with the exception of Antibiogram and Hybrid data if the information is not available.
- Antibiotic susceptibility data should be provided as soon as available.

### C. Risk of extension of the outbreak

- The risk of extension of the outbreak will be assessed through risk factors for cholera transmission in both the area targeted for vaccination and in adjacent areas. These are:
  - the population characteristics (Table 1 in the request form): population density and mobility
  - access to safe water and sanitation (Table 2 in the request form).

The risk of extension will also be assessed in relation to the risk of transmission in areas surrounding those already affected by the outbreak thus information on population characteristics and water and sanitation is requested also for adjacent areas to those where vaccination is planned.

- **Improved vs Unimproved water supply/sanitation (Table 2 of the request form):** Following the two definitions of improved drinking-water sources and improved sanitation facilities, the WHO / UNICEF Joint Monitoring Program (JMP) for Water Supply and Sanitation has defined a list of drinking-water and sanitation categories that can be considered improved or unimproved (Please see Annex B of this document).

- **Hygiene** is not included in Table 2 of the request form because there are no clear indicators to measure level of personal hygiene. Hygiene promotion interventions are important however, and should be described in Tables 4 and 5 of the request form.

### D Capacity to control the outbreak

- The mainstays of control measures to be implemented during an ongoing epidemic should remain (i) the provision of appropriate treatment to people with cholera, (ii) interventions to improve access to water and sanitation and (iii) the mobilization of communities (Tables 3, 4, 5 in the ICG request form). The use of OCV should not divert attention away from these standard control interventions.
• The capacity to implement standard cholera control measures will influence the risk of extension of the outbreak. It is important that these are described well to inform the vaccination strategy and help prioritize if necessary.

### E. Cold chain

• The feasibility of an immunization campaign will depend to a great extent on the cold chain capacity and logistics organization.
• The Excel spreadsheet contains a Logistics tool (please see worksheet entitled “OCV logistics”) that calculates automatically, using the data entered in Annex 4, the cold chain storage and transport requirements for Shanchol™. It also provides general information about packing volumes.
• The target population entered in “Annex 4 Vaccine needs” will automatically appear in “OCV logistics”. You cannot enter any information directly into the “OCV logistics” worksheet.
• Use the OCV Logistics worksheet to inform your answers in Section E of the request form.

### F. Planned OCV vaccination campaign

• The vaccination plan, in addition to the information provided in this section and Annex 4, will assist the ICG in assessing the feasibility of the OCV campaign.
• Annex C contains an outline of the information that should be included in the vaccination plan.
• To calculate the vaccine needs the target population is multiplied by 2 as there are 2 doses of vaccine per person.

### G. Licensing/registration of product in country

• Only vaccine pre-qualified by the WHO will be available in the OCV stockpile. There are currently three orally-administered cholera vaccines produced at industrial scale in the world, two of which are pre-qualified by WHO: Dukoral® and Shanchol™.
• The characteristics of Dukoral® and Shanchol™ are described in Annex D of this document. Assume the vaccine to be deployed will be Shanchol™ unless otherwise notified.
• Information on registration status of cholera vaccines in the country is necessary to prepare importation and custom clearance of OCV from the emergency stockpile.

### H. Vaccine stockpiles in the country

• If there is a stockpile of OCV readily available in the country, the ICG may deploy vaccine from the emergency stockpile to complete the needs of vaccine not met by the in-country stockpile.
• Specify the vaccine type(s), number of doses and expiry date(s) in Section H of the request form.

### I. Request for advance of Operational Costs Support

• If support for operational costs is needed, complete Annex 5 of the Excel spreadsheet and specify the operational costs for which an advance is requested and which costs the country will cover. Other budget formats may be used as long as the information in Annex 5 is included as a minimum.
To estimate the budget and operational costs, assume the vaccine is Shanchol™. The ICG Secretariat will inform you if Shanchol™ is not available for deployment at the time of the request.

J. Reimbursement

- The funds for reimbursement of the ICG should be identified during the process of making the request to the ICG if not before.
- If you are seeking funding from a donor (for example, CERF or ECHO), effort should be made to contact them during the outbreak to be eligible for emergency response funds.
- To estimate the costs of vaccine, assume the vaccine is Shanchol™. The ICG Secretariat will inform you if Shanchol™ is not available for deployment at the time of the request.

K. Monitoring and Evaluation (M&E)

- Evaluating the usefulness of OCV as part of an outbreak response plan is crucial to guide future cholera control strategies.
- The Monitoring and Evaluation document contains the information to be collected for the purpose of monitoring and evaluating the campaign. This information should be compiled after the completion of the second phase of the vaccination campaign (2nd dose) and sent to the ICG Secretariat. You may use another format for the report as long as all of the information contained on the M&E form is included.
## ANNEX A: Epidemiological and demographic considerations for OCV stockpile deployment

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Indicator</th>
<th>Decision threshold</th>
<th>Potential impact of vaccination campaign</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Susceptibility of the population</strong></td>
<td>Number of cases reported in the affected area(s) during the past 2–3 years</td>
<td>No or few cases reported</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td></td>
<td>High number of cases reported</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Attack rate of previous outbreaks in the affected area(s)</td>
<td>High attack rate</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Low attack rate</td>
<td>X</td>
</tr>
<tr>
<td><strong>Vulnerability of the population</strong></td>
<td>Case-fatality rate (CFR) of previous outbreaks in the affected area(s)</td>
<td>High CFR</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Low CFR</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Refugee camp, internally displaced people, or slums present in the affected area(s)</td>
<td>Yes</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Area(s) with important population movements (border, market hub, etc.)</td>
<td>Yes</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Population density in affected area(s)</td>
<td>High density</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Low density</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Access to water, sanitation, hygiene, and health care?</td>
<td>Poor access</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Good access</td>
<td>X</td>
</tr>
<tr>
<td><strong>Risk of spatial extension</strong></td>
<td>Time elapsed / maturity of the outbreak since first case reported</td>
<td>Few weeks</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Few months</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Attack rate since the start of the current outbreak (i.e. cumulative cases)</td>
<td>Low attack rate</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td></td>
<td>High attack rate</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Proportion of health units in the district reporting cases</td>
<td>Low proportion</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td></td>
<td>High proportion</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Time at which first cases were notified</td>
<td>First cases notified</td>
<td>X</td>
</tr>
</tbody>
</table>
Note: An epidemic threshold is not established to define a cholera epidemic. Deployment of oral cholera vaccine depends on a combination of factors as described in this table.

<table>
<thead>
<tr>
<th></th>
<th>during the epidemic season</th>
<th>early in the season</th>
<th>late in the season</th>
</tr>
</thead>
<tbody>
<tr>
<td>First cases notified</td>
<td>X</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

a. The calculation of attack rates will rely on the availability of population figures. In some instances, cholera attack rates are overestimated because all cases of acute watery diarrhoea are included in the numerator. In general, the quality of the data should be checked when using this indicator. According to Médecins Sans Frontières (MSF) guidelines, the maximum expected attack rate (i.e. the “worst case scenario”) would be 5% of the entire population in refugee settings and urban slums, and 2% in rural areas. These figures might be exceeded in a completely naive population, for example in 2010 in Haiti.

b. The CFR is likely to be underestimated if all cases of acute watery diarrhoea (and not only cases of cholera) are included in the denominator. Only deaths occurring in health-care facilities are usually reported. In general, the quality of the data should be checked when applying this indicator. According to WHO, CFR should remain below 1% with proper treatment.

c. The duration of cholera outbreaks within a given area present a high degree of variability.

d. The localisation of the health units is used as a proxy indicator for the localisation of the cases to estimate the current extension of the outbreak, because the exact addresses of cases would most likely be unavailable at national level. Countries applying for stockpile vaccines should actively seek reliable information about cases of acute watery diarrhoea from all health units in the affected district(s).

e. In some areas, cholera outbreaks occur on a regular basis, every year or so, usually during the rainy season.
ANNEX B: List of drinking-water and sanitation categories that can be considered improved or unimproved

Website: http://www.wssinfo.org/definitions-methods/watsan-categories/

Water supply

- "Improved" sources of drinking-water:
  - Piped water into dwelling, also called a household connection, is defined as a water service pipe connected with in-house plumbing to one or more taps (e.g. in the kitchen and bathroom).
  - Piped water to yard/plot, also called a yard connection, is defined as a piped water connection to a tap placed in the yard or plot outside the house.
  - Public tap or standpipe is a public water point from which people can collect water. A standpipe is also known as a public fountain or public tap. Public standpipes can have one or more taps and are typically made of brickwork, masonry or concrete.
  - Tubewell or borehole is a deep hole that has been driven, bored or drilled, with the purpose of reaching groundwater supplies. Boreholes/tubewells are constructed with casing, or pipes, which prevent the small diameter hole from caving in and protects the water source from infiltration by run-off water. Water is delivered from a tubewell or borehole through a pump, which may be powered by human, animal, wind, electric, diesel or solar means. Boreholes/tubewells are usually protected by a platform around the well, which leads spilled water away from the well head.
  - Protected dug well is a dug well that is protected from runoff water by a well lining or casing that is raised above ground level and a platform that diverts spilled water away from the well. A protected dug well is also covered, so that bird droppings and animals cannot fall into the well.
  - Protected spring. The spring is typically protected from runoff, bird droppings and animals by a "spring box", which is constructed of brick, masonry, or concrete and is built around the spring so that water flows directly out of the box into a pipe or cistern, without being exposed to outside pollution.
  - Rainwater refers to rain that is collected or harvested from surfaces (by roof or ground catchment) and stored in a container, tank or cistern until used.

- "Unimproved" sources of drinking-water:
  - Unprotected spring. This is a spring that is subject to runoff, bird droppings, or the entry of animals. Unprotected springs typically do not have a "spring box".
  - Unprotected dug well. This is a dug well for which one of the following conditions is true: 1) the well is not protected from runoff water; or 2) the well is not protected from bird droppings and animals. If at least one of these conditions is true, the well is unprotected.
  - Cart with small tank/drum. This refers to water sold by a provider who transports water into a community. The types of transportation used include donkey carts, motorized vehicles and other means.
  - Tanker-truck. The water is trucked into a community and sold from the water truck.
  - Surface water is water located above ground and includes rivers, dams, lakes, ponds, streams, canals, and irrigation channels.
- Bottled water is considered to be improved only when the household uses drinking-water from an improved source for cooking and personal hygiene; where this information is not available, bottled water is classified on a case-by-case basis.
Sanitation

- **"Improved" sanitation:**
  - Flush toilet uses a cistern or holding tank for flushing water, and a water seal (which is a U-shaped pipe below the seat or squatting pan) that prevents the passage of flies and odours. A pour flush toilet uses a water seal, but unlike a flush toilet, a pour flush toilet uses water poured by hand for flushing (no cistern is used).
  - Piped sewer system is a system of sewer pipes, also called sewerage, that is designed to collect human excreta (faeces and urine) and wastewater and remove them from the household environment. Sewerage systems consist of facilities for collection, pumping, treating and disposing of human excreta and wastewater.
  - Septic tank is an excreta collection device consisting of a water-tight settling tank, which is normally located underground, away from the house or toilet. The treated effluent of a septic tank usually seeps into the ground through a leaching pit. It can also be discharged into a sewerage system.
  - Flush/pour flush to pit latrine refers to a system that flushes excreta to a hole in the ground or leaching pit (protected, covered).
  - Ventilated improved pit latrine (VIP) is a dry pit latrine ventilated by a pipe that extends above the latrine roof. The open end of the vent pipe is covered with gauze mesh or fly-proof netting and the inside of the superstructure is kept dark.
  - Pit latrine with slab is a dry pit latrine whereby the pit is fully covered by a slab or platform that is fitted either with a squatting hole or seat. The platform should be solid and can be made of any type of material (concrete, logs with earth or mud, cement, etc.) as long as it adequately covers the pit without exposing the pit content other than through the squatting hole or seat.
  - Composting toilet is a dry toilet into which carbon-rich material (vegetable wastes, straw, grass, sawdust, ash) are added to the excreta and special conditions maintained to produce inoffensive compost. A composting latrine may or may not have a urine separation device.
  - Special case. A response of “flush/pour flush to unknown place/not sure/DK where” is taken to indicate that the household sanitation facility is improved, as respondents might not know if their toilet is connected to a sewer or septic tank.

- **"Unimproved" sanitation:**
  - Flush/pour flush to elsewhere refers to excreta being deposited in or nearby the household environment (not into a pit, septic tank, or sewer). Excreta may be flushed to the street, yard/plot, open sewer, a ditch, a drainage way or other location.
  - Pit latrine without slab uses a hole in the ground for excreta collection and does not have a squatting slab, platform or seat. An open pit is a rudimentary hole.
  - Bucket refers to the use of a bucket or other container for the retention of faeces (and sometimes urine and anal cleaning material), which are periodically removed for treatment, disposal, or use as fertilizer.
  - Hanging toilet or hanging latrine is a toilet built over the sea, a river, or other body of water, into which excreta drops directly.
  - No facilities or bush or field includes defecation in the bush or field or ditch; excreta deposited on the ground and covered with a layer of earth (cat method); excreta wrapped and thrown into garbage; and defecation into surface water (drainage channel, beach, river, stream or sea).
ANNEX C: OCV Vaccination Campaign Plan Outline

NB. The information 5-8 is additional to the information collected in the OCV ICG request form (1-3.A)

1. **Introduction, Rationale and Objectives**
   - Brief description/analysis of country's cholera situation
   - Regional and district context
   - Objective of mass vaccination
   - Planned vaccination date (please give dates for each round) and expected duration of each round.

2. **Profile of affected area and target population group**
   - Affected population profile: characteristics (e.g. size, age group, concentration, displaced or refugee populations) and risk factors (e.g. latest vaccination, population movements, border regions)
   - Targeted geographical area

3. **Vaccine needs**
   - Target vaccine coverage
   - Calculation of vaccine needs

4. **Organization and coordination**
   - National and local epidemic committee: composition, organisation, role and involvement
   - Partners involved and roles
   - Coordination, water and sanitation, curative
   - Comprehensive outbreak response plan

5. **Selection of Vaccination sites and priority areas**
   - Vaccination sites (in accordance with section 2)
   - Vaccination strategy (fixed sites, mobile posts, or combination)
   - Expected number of vaccinations per day and per team (fixed and mobile sites)

6. **Social Mobilization**

7. **Communication plan**

8. **Micro plan**

   **Organization of the campaign:**
   - Composition and Number of vaccination teams (according to estimated vaccination performance)
   - Vaccination campaign chronogram per sub-district (including start date and duration per sub-district)
   - Supervision (including composition of the team and organization)
   - Training of vaccination and supervisors teams

   **Logistics**
- Cold chain at regional, district and vaccination post level
- Local Transportation
- Waste management: strategy, means, human resources
**ANNEX D. Characteristics of the WHO pre-qualified vaccines**

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Oral cholera vaccines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trade name</td>
<td>Dukoral®</td>
</tr>
<tr>
<td></td>
<td>Shanchol™</td>
</tr>
<tr>
<td>Type of vaccine</td>
<td>Killed whole cell vaccine <em>V.cholerae</em> O1 serogroup + recombinant B subunit of cholera toxin (WC/rBS)</td>
</tr>
<tr>
<td></td>
<td>Killed bivalent (O1 and O139 serogroups ) whole-cell vaccine suspension. (BivWC)</td>
</tr>
<tr>
<td>Presentation (or packaging)</td>
<td>3 ml single dose vials and 5.6 g of effervescent granules of sodium bicarbonate buffer in a sachet</td>
</tr>
<tr>
<td></td>
<td>1.5ml single dose vials (in 3 ml glass vial with aluminium cap)</td>
</tr>
<tr>
<td>Age</td>
<td>From 2 years of age</td>
</tr>
<tr>
<td></td>
<td>From 1 year of age</td>
</tr>
<tr>
<td>Administration course or (Dosing)</td>
<td>-Adults and children 6 years and older: 2 doses given orally 1-6 weeks apart. Booster dose after 2 years.</td>
</tr>
<tr>
<td></td>
<td>-Children 2-5 years: 3 doses given orally 1-6 weeks apart. Booster dose after 6 months.</td>
</tr>
<tr>
<td></td>
<td>-Fasting required 1 hour before and after vaccination.</td>
</tr>
<tr>
<td></td>
<td>2 doses given orally 2 weeks apart. A period of +3 days is accepted for second dose.</td>
</tr>
<tr>
<td></td>
<td>No official recommendation on booster yet.</td>
</tr>
<tr>
<td>Buffer</td>
<td>Dilution in 150ml of water (75ml for children 2-5 years) mixed with buffer</td>
</tr>
<tr>
<td></td>
<td>No buffer needed</td>
</tr>
<tr>
<td></td>
<td>Water may be offered following ingestion of the vaccine, but is not required.</td>
</tr>
</tbody>
</table>
| Protection/efficacy | Earliest onset of protection 7 days after 2nd dose. | Earliest onset of protection 7-10 days after 2nd dose.  
67% protection for at least 2 years in all ages |
|---------------------|---------------------------------------------------|--------------------------------------------------|
| Adverse effects/contraindications | No major adverse effects reported.  
Currently not recommended for use in pregnancy (no specific studies performed)  
Administration may be considered after benefit-risk evaluation.  
Can be given to HIV-infected persons. | No major adverse effects reported.  
Currently not recommended in pregnancy (limited data)  
Currently not recommended in HIV/AIDS or other immuno-compromised states (No clinical data)  
Administration may be considered after benefit-risk evaluation. |
| Shelf life, storage and cold chain | 3 year shelf life at 2-8°C.  
Stable for 1 month at 37°C  
2 weeks at < 27°C  
**Do not freeze**  
No VVM.  
Packed volume per dose: 136cm³ (in 2-dose pack; also available in single and 20-dose pack) | 30 months shelf life at 2-8°C  
**Do not freeze**  
VVM of type 14.  
Stable for 14 days at 37°C  
Packed volume per dose in 35-dose pack: 16.8cm³  
(140 mm x 105 mm x 40 mm) |
| Manufacturer | Crucell, (Sweden) | Shantha Biotechnics, (Hyderabad, India) Sanofi Company |
| Current production capacity (2012) | 2 million doses per year | 2 million doses per year |
| Countries licensed (June 2013) | Licensed in 60 countries | India, Nepal, Malaysia, Philippines, Ivory Coast |
| Year first licensed | 1991 | 2009 |
| Date of WHO prequalification | 25 Oct 2001 | 29 Sep 2011 |
| Estimated prices per dose (2013) | ~ $4.7-9.4 per dose | $1.85 |