EDA Assessment Report for Biological Medicinal Product

(Scientific Discussion)

Poliomyelitis Vaccine
(live, oral attenuated, human Diploid Cell), type 1 and 3

Date: October 2024

Unit: Technical Assessment Unit

Assessment report

Poliomyelitis Vaccine (OPV I ,III)

Administrative information:

Invented name of the medicinal product:	Poliomyelitis Vaccine (live, oral attenuated, human Diploid Cell), type 1 and 3
INN (or common name) of the active substance(s):	OPV Sabin type I 1e+006 CCID50 ; OPV Sabin type III 630957 CCID50 ;
Marketing Authorization holder	Beijing Institute of Biological Products Co., Ltd. – Beijing Economic and Technological Development Area, Boxing 2 Road No.6, 9. - CHINA
Applied Indication(s):	Active immunization against type I & III polioviruses
Pharmaceutical form(s) and strength(s):	Oral vaccine containing suspensions of type I and type III attenuated poliovirus (Sabin strain). Each dose of 2 drops (0.1m) contains: OPV Sabin Bivalent Strain type I and III viruses: not less than 6.21 Lg $CCID_{50}$/dose OPV Sabin Strain type I viruses: not less than 6.00 Lg $CCID_{50}$/dose OPV Sabin Strain type III viruses: not less than 5.80 Lg $CCID_{50}$/dose
Route of administration	oral.
Approved Pack(s):	Carton box containing 3 neutral borosilicate glass vials (60 doses), each of 2ml sealed with chlorinated butyl rubber stopper closure, (slotted type) along with aluminum foil cap and inserted a leaflet

List of abbreviations

OPV	Oral Poliomyelitis Vaccine
$CCID_{50}$	Cell-culture infective dose 50%
CTD	Common technical document
SOPs	Standard operating procedures
tOPV	Trivalent Oral Poliomyelitis Vaccine
bOPV	bivalent Oral Poliovirus Vaccine
mOPVs	monovalent Oral Poliovirus Vaccine
WHO	World Health Organization
RNA	Ribonucleic acid
IgM	Immunoglobulin M
IgG	Immunoglobulin G
CNS	Central nervous system
MA	Marketing authorization
GMP	Good manufacturing practice
IPC	In process controls
QC	Quality control
COA	Certificate of Analysis
TRS	Technical Report Series
CP	Chinese pharmacopeia
BIBP	Beijing Institute Biological Products Co., Ltd.
CFDA	China Food and Drug Administration
$MgCl_2$	Magnesium chloride
Na^+	Sodium ion
K^+	Potassium ion
RPN	risk priority number (a numerical assessment of the risk assigned to a failure mode when conducting a Failure Modes and Effects Analysis (FMEA))
EP	European pharmacopeia
GMT	Geometric Mean of Reciprocal Antibody Titer
CI	Confidence Interval
VAPP	Vaccine assiociated paralytic polio

AEFI	Adverse Events Following Immunization
GPEI	Global Polio Eradication Initiative
WPV1	Wild Type 1 Poliovirus
WPV3	Wild Type 3 Poliovirus
cVDPV	Circulating Vaccine-Derived Poliovirus
IPV	Inactivated Poliomyelitis Vaccine
UNICEF	United Nations Children's Fund
MNVT	monkey neurovirulence test

Dossier initial submission and evaluation process.

- The product was submitted for registration via 343/2021 ministerial decree.
- The dossier evaluation by the registration administration units was started on 16.1.2022 after providing all the required documents according to the Checklist for documents of new biological products registration file.
- Full CTD along with detailed SOPs were provided.

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1. General introduction about the product including brief description of the AI, its mode of action and indications

-OPV was developed in 1961 by Dr. Albert Sabin. OPV contains live-attenuated strains of poliovirus that are also referred to as the "Sabin strains".
-Three forms of OPV are currently available--tOPV, bOPV, and mOPVs--with tOPV being the being the most commonly used form in routine and supplementary immunization activities in low and middle-income countries globally.
-Presence of type II component in the vaccine impairs the immune response to types I and III polio virus requiring more doses of tOPV to reach herd immunity thresholds for those types compared to the number of doses of bOPV to reach those same immunity thresholds.
-Note that all cases of polio related to wild virus are now due to type I virus. Type III was last detected in November 2012, although absence of virus detection for one year is not sufficient for certifying eradication.
-BIBP is willing to participate to the global health effort to eradicate the Poliovirus. Therefore, BIBP has developed a new bivalent OPV vaccine based on its long standing experience in production of tOPV. The bOPV proposed here for WHO prequalification is strictly identical to the tOPV except of removing the Polio type II strain.

2. Quality aspects:

1.2.1 Introduction

As mentioned previously in the aforementioned section.

1.2.2Drug Substance (Active ingredient)

- **General information**

-Polioviruses are among the simplest viruses in terms of genetic complexity and size.
-The RNA genomes from all three serotypes of poliovirus have been cloned and sequenced.
-The genomic RNA is infectious and serves as messenger RNA for viral protein synthesis. The RNA is translated in a single open reading frame into one large polyprotein, which is then processed through proteolytic cleavage by two distinct virus-encoded proteases into the functional viral proteins..

- **Immune response of bOPV:**

-Administration of OPV, similar to natural exposure to polioviruses, initiates a complex process that eventually results in humoral (systemic) and mucosal (local) immunity.
-Production of IgM antibody predominates initially, can be detected as early as 1 to 3 days after infection, and disappears after 2 to 3 months.

-IgG antibody increases during this same period, eventually constitutes the predominant class of persistent antibody, and may last for life. The humoral immune response is not completely serotype-specific, and some degree of cross-protection (heterotypic cross-reaction) has been observed.
-The significance of cell-mediated immunity to poliovirus exposure remains to be shown, although cytotoxic T-cell responses may contribute to the inflammation and cell necrosis that characterize poliovirus infections of the CNS.

- **Manufacture, process controls and characterization:**
  - **Manufacturer**:

Site	Responsibility
Beijing Economic and Technological Development Area, Boxing 2 Road No.6,9. Beijing, P.R.China 100176	Production: The preparation of the final bulk product comprises blending of the active substances, Poliomyelitis (Live) Vaccine Type I Type III (Human Diploid Cell), Oral with the excipients to achieve a homogeneous blend prior to filling into vials. The processing steps include: cell expansion, virus multiplication, harvesting, formulation, filling and packaging.

  - **Description of Manufacturing Process and Process Controls**

The company has provided detailed process flow chart in the MA file that summarizes the following information as showing below:

- Detailed sequence of process steps for the complete manufacturing process;
- Identification of the room in which a certain process step takes place;
- GMP and biosafety classification of the rooms;
- Used materials, buffers, media, etc. for each process step;
- Used major equipment;
- IPC and QC test;
- Intermediates and allowed storage times/temperatures for intermediate

- **Control of Materials**

-Specifications, supplier and manufacturer details are provided for all raw materials (Chemical Materials and Biological Raw Materials) used in the production of Poliomyelitis (Live) Vaccine Type I Type III bulk.
-COAs for materials were provided as well TSE/BSE Freedom statements are provided for materials of animal origin or suspected, i.e.: New-born Calf Bovine Serum , Trypsin and Lactalbumin Hydrolysate.
-in addition, both Master virus seed lots & working virus seed lots are well characterized and tested.

- **Controls of Critical Steps and Intermediates**

-Quality-control (QC) release tests performed on the intermediates isolated during the manufacturing process of the drug substance as well The specifications for the Type I and Type III Single Harvest Intermediate , Monovalent Bulk , Monovalent Final Bulk and Brief description of the methods used for testing intermediates are established according to WHO TRS980, and to the monograph for Oral Poliomyelitis Vaccines in Chinese Pharmacopoeia 2015 Therefore its specifications meet both WHO and CP requirements.

- **Process Validation**

-To ensure the process can produce the safe, effective and quality products, the following validation for consistent batches of the process was conducted. A minimum of 3 continuous batches were a part of the validation strategy for consistency batches of OPV
-The batch size for process validation is always the same with commercial batches.
-The validation of production processes, cleaning procedures, analytical methods, in-process control test procedures, computerized systems, and persons responsible for design, review, approval and documentation of each validation phase are well documented.

- **Manufacturing Process Development**

-The manufacturing process of Poliomyelitis (Live) Vaccine Type I Type III (Human Diploid Cell), Oral developed by Beijing Institute of Biological Products Co., Ltd. (hereinafter referred to as BIBP) is consistent with that of the existing Poliomyelitis (Live) Vaccine (Human Diploid Cell), Oral (trivalent, Approval No.: 2015B01160) produced by our company with the approval by China Food and Drug Administration (CFDA).
-China initially used monovalent or bivalent OPV vaccine for production. Since 1983, Human Diploid Cell (2BS strains) has been used to produce tOPV dragee candies in China.
-The vaccine has been extensively administered in China for a long time. So far, it has been used for 59 years, amounting to nearly 3 billion doses of OPV for China.

The eradication of polio in China is closely associated with OPV dragee candies (Human Diploid Cell), which fully demonstrates the safety and effectiveness of dragee candies and further confirms that our production process is applicable to vaccine production.
-For Poliomyelitis (Live) Vaccine Type I Type III (Human Diploid Cell), Oral, cell factory is adopted for cell culture and virus inoculation. The manufacturing process of the virus bulk is the same with that of the mOPV (Human Diploid Cell).

- **Characterization**

-Polioviruses and the enteroviruses are distinguished from the other picornaviruses on the basis of physical properties such as buoyant density in caesium chloride and stability in weak acid.
-The three poliovirus serotypes are distinguished from the other enteroviruses by neutralization with serotype-specific antisera and the propensity to cause paralytic illness. The Mahoney strain of type I poliovirus is the prototype for the polioviruses, the genus enterovirus, and the family Picornaviridae. It is among the most-studied and best-characterized agents of human disease.
-the viral genome consists of a single molecule of ribonucleic acid (RNA), which is about 7500 nucleotides long.
-OPV is administered orally and there is no purification process in the OPV manufacturing and also no QC impurity testing. A lot of process parameters have no impact on the product quality, only on its quantity. Therefore, the compatibility study is not conducted

- **Specification**

- Specifications of the Monovalent Bulks and Monovalent Final Bulk of Type I and Type III are established according to WHO TRS980.
-including tests for safety & identity of bulks.
-Fully detailed analytical procedures for the tests performed on vaccine bulk and Testing SOP for bOPV intermediate product are provided in the MA file.
-validation reports are attached with the MA file.

- **Batch analysis**

-Batch Analysis description of the three Monovalent Bulk and Monovalent Final Bulk are provided and found to be complied with the predefined acceptance criteria.

- **Reference Standards or Materials**

-list of the reference standards that used for testing are provided in the MA file.

- **Container closure system**

-10L vaccine vessel (NALGENE®, 10L PC Carboy, and catalog no.2251-0020) is used for storage of bOPV intermediates.
-Characterization and COA are provided.

- **Stability of drug substance**

Based on available stability data

✓ **Required Shelf Life:**

- Monovalent final bulk: 24 months
- Bivalent final bulk: 72 hours

✓ **Suggested Storage Conditions:**

- Monovalent final bulk: ≤ -20 °C
- Bivalent final bulk: 2~8 °C

2.2.3 Drug product:

- **Description and Composition of the Drug Product:**

-Poliomyelitis (Live) Vaccine Type I Type III (Human Diploid Cell), Oral (hereinafter referred to as bOPV) is a vaccine containing suspensions of type I and type III attenuated poliovirus (Sabin strain).
-The attenuated virus particles in bOPV are harvested from Human diploid cell cultures. The product prepared by inoculation of the type I and III attenuated polio virus strains into the human diploid cells, and then culturing and harvesting the virus fluid, is a reddish orange, clear liquid without visible particle. 1 Molar Magnesium chloride as a stabilizer. The vaccine comes in vials of 20 doses.

- **Pharmaceutical Development**

- **Components of drug product**

-Virus strain
Polio virus seed (Sabin strain) type I: Mahoney strain, LS-c, 2ab/KP3
Polio virus seed (Sabin strain) type III: Leon strain, 12a,b/KP4
-Monovalent bulk
Monovalent bulk of Poliomyelitis (Live) Vaccine Type I Type III (Human Diploid Cell), Oral
-Monovalent final bulk

Monovalent final bulk of Poliomyelitis (Live) Vaccine Type I Type III (Human Diploid Cell), Oral

-Magnesium chloride ($MgCl_2$) as excipient alone is currently used to stabilize Sabin oral poliovirus vaccine against loss of poliovirus infectivity.

-A study shows that the conformation of poliovirus capsid is sensitive to $MgCl_2$ salt, and that the rigidity of poliovirus conformation is increased in its presence.

-$MgCl_2$ is able to lessen the extent of water penetration into poliovirus capsids and to diminish the swelling of the capsid.

-The thermos stability of poliovirus could be promoted by specific ionic interaction in the case of $MgCl_2$.

-Furthermore, ionic interaction of Mg^{2+} with negatively charged poliovirus surface is expected to play an important role. $MgCl_2$ may also exhibit some specificity to the virus assembly, since poliovirus capsid contains Na^+, K^+ in addition to Mg^{2+}

- **Formulation Development**

- BIBP has been an historical Polio vaccine in China since 1960s. It has produced and licensed a trivalent OPV widely use in the country.

BIBP is willing to participate to the global health effort to eradicate the Poliovirus. Therefore, BIBP has developed a new bivalent OPV vaccine based on its long standing experience in production of tOPV. The bOPV proposed here for WHO prequalification is strictly identical to the tOPV except of removing the Polio type II strain.

Production of Poliomyelitis vaccine (OPV vaccine) started in China since 1960s, BIBP is the first company who develops and produces live attenuated Poliomyelitis vaccine, and the only company in Chinese market obtaining manufacturing licensure for bOPV.

- The evolution of Poliomyelitis is described in details in the MA file.

-The route of administration for bOPV is oral, by providing two drops (≈ 0.1 mL) of bOPV contained in multidose vials produced by BIBP. Although in the early 1960s China put OPV into dragees. Liquid bOPV has been licensed to use in China for routine vaccination since 2016.

- **Manufacturing Process Development**

-The manufacturing process of bOPV monovalent bulk is not changed prior to marketing. However, two changes are made to bOPV prior to marketing including manufacturing process change and raw materials supplier change. The manufacturing process change that is introduction of sterilization filtration into the bivalent final bulk formulation step is made

for increase the sterility assurance level for the product. Moreover, pH measurement is added as one of the final product release test in light of WHO technical report No.904.

- **Microbiological Attributes**

-It can be found that resuscitation of cell, cell passage, virus inoculation, virus harvesting, preparation of monovalent final bulk, preparation and filling of bivalent final bulk, a total of 7 procedures need sterility assurance, while the packaging process does not. Therefore, the risk assessment of sterility assurance for personnel, materials and environment is involved in the eight processes.
-Through the risk assessment, it was found that none of the production procedures of Poliomyelitis (Live) Vaccine (Human Diploid Cell) has RPN ≥ 9 under the existing sterility assurance; 88 procedures have RPN <9, the risk is acceptable, and no measures are needed..

- **Compatibility**

-OPV is administered orally and there is no purification process in the OPV manufacturing and also no QC impurity testing. A lot of process parameters have no impact on the product quality, only on its quantity. Therefore, the compatibility study is not conducted.

Manufacture of the drug product:
Description of manufacturing process and process controls along with manufacturers and responsibilities.

- **Manufacturer**:

-Manufacturer： Beijing Institute of Biological Products Co., Ltd.
-Product: Poliomyelitis (Live) Vaccine Type I Type III (Human Diploid Cell), Oral
-Production: The preparation of the final bulk product comprises blending of the active substances, Poliomyelitis (Live) Vaccine Type I Type III (Human Diploid Cell), Oral with the excipients to achieve a homogeneous blend prior to filling into vials. The processing steps include: cell expansion, virus multiplication, harvesting, formulation, filling and packaging.
-Address: Beijing Economic and Technological Development Area, Boxing 2 Road No.6,9.
Beijing, P.R.China
100176

- **Control of critical steps and intermediates**

-The specifications of the **Bivalent Final Bulk** is established according to WHO TRS980, "Recommendation to Assure the Quality, Safety and Efficacy of Poliomyelitis Vaccines

(Oral, Live and Attenuated)" and to the monograph for Oral Poliomyelitis Vaccines in "Chinese Pharmacopoeia"2015 edition. Therefore its specifications meet both WHO and CP requirements.

- **Process validation and / or evaluation**

-To ensure the process can produce the safe, effective and quality products, minimum of 3 continuous batches were a part of the validation strategy for consistency batches of OPV (human diploid cell), the final bulk production in the upstream and filling process included both.

- **Product specification:**

-some specifications proposed for release and stability testing of the finished product comply with Chinese pharmacopia & WHO TRS 980
-Detailed SOPs ,validation protocols & reports are provided.
-The specifications include identity& safety of the drug product.
-Justification of the drug product specifications at the release and during stability studies are provided.
-Materials applied as excipients in the formulation of final bulk include the Magnesium Chloride Hexahydrate, is used to prepare the 4.5M $MgCl_2$ solution for the bivalent bulk formulation process during the routine production of the batches of bivalent Poliomyelitis (Live) Vaccine Type I Type III, Oral. Therefore its specifications meet EP and CP or Chinese national standard requirements.

- **Reference Standards or Materials.**

-List of references used for each test are mentioned in the MA file.

- **Container closure system**

-The primary package is a 2.0 mL neutral borosilicate glass vial containing a standard product information label. Each 2.0 mL glass vial is sealed with chlorinated butyl rubber stopper closure, (slotted type) along with aluminum foil cap.
-bOPV Sabin 20 Dosage Packaging Specifications have been well described in the MA file.

- **Stability of the drug product**

-Based on available stability data,

- ✓ **approved Shelf Life :** 24 months

- ✓ **approved Storage Conditions:**

-Vaccine is potent if stored at minus 20 °C or below until the expiry date indicated on the vaccine vial label. It can be stored for up to six months between (2 - 8 °C), or can be re-frozen at minus 20 °C for up to six months.

- ➢ **Adventitious agents:**

-as mentioned in the microbiological attributes section.

3. Non –clinical aspect:

Since Poliomyelitis Vaccine is an oral vaccine and human is the only host for the poliomyelitis virus, and because the vaccine was prepared from the bulk of live attenuated poliomyelitis vaccine type I and live attenuated poliomyelitis vaccine type III on the basis of the existing oral live attenuated poliomyelitis vaccine product that proved that the product is safe and effective as claimed by the applicant; pre-clinical animal studies such as efficacy, acute toxicity or allergic stimulation studies have not been carried out for the vaccine, however according to requirements of WHO TRS No. 980, 2014 "WHO Expert Committee on Biological Standardization" and "Chinese Pharmacopoeia" (2015 version), an experiment of monkey neurovirulence study (MNVT) for each batch of bulk for each type of vaccine during the production process is conducted to evaluate the safety of the bulk.

Each batch of bOPV has been tested MNVT during bulk stage, it has been completed for all batches of products during the past three years and testing results were as follows; Before conducting MNVT monkeys were negative for polyominoes virus. After inoculation, no concurrent infection was observed. The clinical observation revealed normal signs and the pathological section showed results within the qualified range. Several batches of type I bulk as well as of type III bulk showed excellent safety.

4. Clinical aspect

- **Clinical Pharmacology conclusion:**

Pharmacodynamics & Pharmacokinetics: Not applicaple according EMEA/CHMP/VWP/164653/05 Rev. 1

- **Clinical Efficacy conclusion:**

In the clinical study in China, Serum conversion rate and 4-fold growth rate: The type I & III serum conversion rate (4-folds growth rate) of the trial vaccine groups (the 2wIPV+bOPV group and the wIPV+2bOPV group) showed no significant difference from that of the control vaccine group (2wIPV+tOPV/wIPV+2tOPV) and those of other groups, and the type I & III serum conversion rate (4-fold growth rate) of the bOPV sequential group was not inferior to that of the tOPV sequential group; The type II serum conversion rate (4-folds increase rate) of the group 2wIPV+bOPV also showed no significant difference from that of the tOPV sequential group and those of other control groups like IPV/OPV, and only the type II serum conversion rate (4-fold growth rate) of the wIPV+2bOPV group was lower than those of the other groups, with significant difference.
(2wIPV+tOPV/wIPV+2tOPV) and the tOPV control group, which, however, was higher than that of the wIPV group; The type III antibody GMT of the group 2wIPV+bOPV was higher than that of the group wIPV+2bOPV, and also significantly higher than that of the sequential group tOPV as well as the control groups wIPV and tOPV; The type II antibody GMT of the 2wIPV+bOPV was higher than that of the group wIPV+2bOPV, and the type II antibody GMT of the sequential group bOPV was significantly lower than that of the sequential group tOPV and those of the control groups wIPV and tOPV.

In the clinical study in Kenya, BIBP two batches of products have good consistency between batches. The criterion for non-inferiority to the comparator vaccine was that the lower limit of the 2-sdied 95% CI for the difference in proportions between the BIBP bOPV and the comparator vaccine be greater than -10 percentage points.
The difference (and 95% CI) for type 1 was 1.5 (-0.5 to 4.6) and for type 3 was 2.2 (-0.1 to 5.6). Seroconversion rates in the BIBP arms were high (greater than 98% for both serotypes in both lots) and never less than that of the control arm. Further, post-vaccination seroprotection rates were also very high (99.1% for both serotypes). The prespecified criteria for non-interference for hepatitis B vaccine were met. For HBV, the results were consistent across the arms of the study at both sites. Seroprotection rates for the BIBP and control arms were not significantly different: 93.7% and 93.8%, respectively. The difference in percentage points (and 95% CI) was -0.09 (-3.86 to 4.48). Similarly, the GMTs were similar, with the ratio (and 95% CI) of the BIBP to control arms 1.20 (0.89 to 1.63).

- **Clinical Safety conclusion:**

In the clinical study "001ID" in China: The severity levels of the common adverse reaction symptoms like **fever** and **diarrhea** were mainly Class 1 or Class 2. The adverse reactions mainly happened in the period from the 0 to 14th day, and the incidence rates of the trial group and control group showed no statistically significant difference.

Serious adverse events were reported to happen on a total of 24 persons, with severity levels of Class 2 or Class 3; All the Serious adverse events showed no correlation with the inoculation/vaccination.

In the clinical study" 002ID" in Kenya, The safety profiles of the BIBP and comparator vaccines were comparable.

The proportions of infants for whom unsolicited adverse events, in general, and SAEs were reported were similar between the BIBP and control arms.

- This study was found in the submitted data, **the Regular Safety Update Report on Bivalent Oral Poliomyelitis Vaccine Type I and III (Human Diploid Cells) (bOPV) period (Nov. 19, 2015 -Nov. 18, 2019)** the Company received :

- **43 death case reports**. Through comparison of place of birth, sex, date of birth, date of vaccination, product batch number, date of AEFI, and simultaneous vaccination, 3 duplicated cases were excluded and 40 death case reports were received. Classification of 40 reports by AEFI type: 24 cases of coincidental events (23 cases with clear evaluation conclusions, respectively from annual feedback from the drug regulatory agency (16 cases) and spontaneous reports (7 cases); one case without a clear diagnosis conclusion, evaluated by the Company based on the autopsy conclusion); 10 cases that could not be evaluated due to incomplete information (2 cases without autopsy, 7 cases from CDC annual feedback, and one case from ADR monthly feedback); 3 cases not excluded; and 3 cases of adverse evenrs.
- The Company has received one suspected mass **VAPP** event. China Food and Drug Administration notified the Company of it in Sep. 2016. Through investigation, among the 11 suspected cases, 3 cases were diagnosed as adverse events of VAPP, 3 cases were not excluded, and 5 cases were not excluded, and 5 cases were coincidental events.

2. General Conclusion and Recommendations if any:

1. PSUR should be submitted to pharmacovigilance, In case of appearance of serious event(s) should be notify regarding these case (s) based on the submitted data of **Regular Safety Update Report on Bivalent Oral Poliomyelitis Vaccine.**
2. The vaccination schedules with bOPV followed by one or 2 doses of IPV were recommended to substitute for vaccinations involving tOPV without compromising the immunogenicity and safety in the population. The findings will be essential for policy formulation by national and global authorities to facilitate polio elimination.
3. In developing countries, the acceptability of injection is limited compared with the oral route mainly due to poor clinical practices, higher cost, and occasional pain and bleeding, which may reduce the pace of introducing IPV globally and may ultimately impact the elimination of poliovirus. Increased availability and affordability of IPV in developing countries will be important prerequisites to ensure global withdrawal of the tOPV. The proportion of children using IPV is increasing each year in China, which is consistent with the introduction of IPV that is called for by the Polio Eradication Endgame Strategic Plan. GPEI report indicated that 7 countries which have not already received their first IPV shipment through UNICEF (United Nations Children's Fund) and were considered at low risk for polio outbreaks will be delayed to introduce IPV until the first quarter of 2017.
4. In April 2016 a switch was implemented from trivalent OPV to bivalent OPV in routine immunization programmes .Following WPV1 and WPV3 eradication, use of all OPV in routine immunizations will be stopped.The switch from trivalent OPV to bivalent OPV is associated with significant public health benefits. More 90% of all cVDPV cases, currently caused by the type 2 component of trivalent OPV, and up to 38% of all VAPP cases, will no longer occur. In addition to these significant humanitarian benefits, OPV type 2 cessation will provide the GPEI with a ‘push’ for global OPV cessation of all OPVs. Feasibility of OPV cessation was underscored in practice, and ensured a ‘trial run’ for all OPV cessation. Key lessons were learnt to ensure that this process can be implemented in the safest and most efficient manner.
5. Based on the above mentioned points (3,4) it was recommended to reduce usage of Oral poliomyelitis vaccine