T-22014/07/2022-Imm
Government of India
Ministry of Health & Family Welfare
Immunization Division
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Nirman Bhawan, New Delhi
Dated: 22nd **March, 2023**

To

State Immunization Officers,
All State/UTs

Subject: Guideline on the usage of the new presentation of Rotavirus Vaccine (RVV) – Rotavac, manufactured by M/s BBIL with VVM on the label of the vaccine vial.

Sir/ Madam,

It is to inform you that as per Letter no F.NO. 12-64/BBIL/PAC-Rotavirus Bulk/17-BD dated 20th Mar'20 issued by CDSCO, the following two updates on the product insert related to Rotavac-(Oral) manufactured by M/s BBIL has been acknowledged-

1. Inclusion of Multi-dose vial policy
2. VVM2 dot is at part of the label.

In view of the above, "New presentation of Rotavac with VVM on the Label of the vaccine vial" will henceforth be supplied under UIP. The Open vial policy/multi-dose policy is applicable to this new presentation of Rotavac vaccine with VVM on the label of the vaccine vial. The new presentation of Rotavac to be stored at -15°C to -25 °C, till district stores and then at 2 °C to 8 °C at the sub-district level. The vaccination schedule of the new presentation will remain the same i.e.- 3 dose schedule at 6 weeks, 10 weeks and 14 weeks.

With the introduction of this "*New presentation of Rotavac with VVM on the Label of the vaccine vial*", there are now two different presentations of Rotavac under the program, i.e-**:**

1. **Rotavac with VVM on the cap of the vaccine vial (Open Vial Policy is not applicable)**
2. **"*New presentation of Rotavac with VVM on the Label*" of the vaccine vial (Open Vial Policy is applicable) comparison of same is put under (Annexure-I)**

Henceforth, for those states that have received/will receive Rotavac with VVM on the label, the following guiding principle for the use may be noted:

- The vial of the **"*New presentation of Rotavac with VVM on the Label of the vaccine vial*"** must be marked with the date and time of opening at first use. The opened/used vial can be used up to four weeks (28 days) as per the open vial policy guideline as annexed **(Annexure-II)**. It may be kindly noted that the old presentation of Rotavac, with VVM on the cap, has to be used within 4 hours of the opening of the vial.

- It is desired that the Rotavac with VVM on the cap already available in the state should be exhausted completely following the EEFO and then only the ***"New presentation of Rotavac with VVM on the Label"*** should be supplied. This will also avoid any confusion among the front-line health workers.
- No session site should have both the new and the old products of RVVV at the same time.
- The new presentation of Rotavac to be used only when the older presentation of Rotavac has dried out/utilised.
- During the transition from the old to the new presentation of Rotavac, kindly ensure the availability of RVV at session site.
- Infants can be immunized with any of the two presentations and complete the dose schedule e.g. If a child has received the first dose from Rotavac with VVM on the cap, then the child can complete the schedule with the new presentation of Rotavac if the old product has been exhausted.
- The entry of ***"New presentation of Rotavac with VVM on the Label of the vaccine vial"*** on eVIN should be done separately under the respective material list (Annexure-III).

Please find annexed **(Annexure-II)** the detailed document for the Open vial policy for further dissemination at all levels. The orientation and review of the implementation of the revised open vial policy should be done with each unit for a smooth transition. Orientation training on the above changes is being planned by Immunisation Division and details of the same will be intimated shortly.

We look forward to disseminating the information to all districts and concerned vaccine handlers for effective implementation of the open vial policy for New presentation of Rotavac with VVM on the label, in your State/UTs.

Yours faithfully

22/3/23

Dr. Veena Dhawan
Additional Commissioner (Imm)

Enclosure-

1. **Annexure-I- Comparative Table of two presentations of Rota Vac Vaccine.**
2. **Annexure-II- Guideline on Open Vial Policy for using multi-dose vials in Universal Immunisation Program.**
3. **Annexure-III: SOP for new Rotavac (dose) material with VVM on label for eVIN.**

Copy to:

- PPS to AS&MD-(NHM), MoHFW.
- PPS to JS-RCH, MoHFW.
- Mission Directors all States/UTs.
- All In-charges of GMSDs.
- Representative - JSI/UNICEF/UNDP/WHO.

Annexure-I- Comparative Table of two presentations of Rota Vac Vaccine.

Rotavac old Product (manufactured by M/s BBIL)	**Rotavac New Product (manufactured by M/s BBIL)**
VVM on the Cap	**VVM on the Label** of the vaccine vial
Open Vial Policy is **not applicable.**	Open Vial Policy **is applicable**.
	

Annexure-II

Guideline on Open Vial Policy for using multi-dose vials in Universal Immunisation Program with inclusion of RVV

Implementation of Open Vial Policy allows reuse of partially used multi dose vials of applicable vaccines under UIP in subsequent session (both fixed and outreach) up to four weeks (28 days) subject to meeting certain conditions and thus reduces vaccine wastage.

Open Vial Policy is applicable on DPT, Td, Hepatitis B, Oral Polio Vaccine (OPV), Haemophilus influenzae type B (Hib) containing Pentavalent vaccine, Injectable-Inactivated Poliovirus Vaccine (IPV), RVV (Rotavac with VVM on Label), JE- (Inactivated), and PCV.

Open Vial Policy does not apply to MR, RVV (RotaSil & Rotavac - with VVM on cap) and BCG vaccines.

As a basic principle open vial policy is not applicable to vaccines with VVM on cap and on vaccine supplied in single-dose presentation.

Uniform and complete adherence to the guidelines for implementation of open vial policy is critical to ensure optimal utilization of UIP vaccines with minimal wastage. Strict vigilance including accurate documentation at all levels is the key to this activity.

A: *Conditions that must be fulfilled for the use of open vial policy:*

1. Any vial of the applicable vaccines opened/used in a session (fixed or outreach) can be used at more than one immunization session up to four weeks (28 days) provided that:
   I. The expiry date has not passed.
   II. The vaccines are stored under appropriate cold chain conditions both during transportation and storage in cold chain storage points.
   III. The vaccine vial septum has not been submerged in water or contaminated in any way.
   IV. Aseptic technique has been used to withdraw vaccine doses. (That is needle/septum has not been contaminated in any way)
   V. The Vaccine Vial Monitor (VVM), is in Usable stage.

2. **Discard the vaccine vial in case any one of the following conditions is met:**
   I. Expiry date has passed.
   II. VVM reached/crossed discard point (for freeze-dried vaccine, before reconstitution only) or vaccine vials without VVM or disfigured VVM.
   III. No label/partially torn label and/or writing on the label not legible.
   IV. Any vial thought to be exposed to non-sterile procedure for withdrawal.
   V. Open vials that have been under water or vials removed from a vaccine carrier that has water.
   VI. If the vaccine vial contains floccules or any foreign body.
   VII. If there is a breakage in the continuity of the vials (crack/leaks).
   VIII. If there is any reported AEFI following use of any of the vaccine vial, do not use it, and retain it safely in proper cold chain and properly sealed zipper bag earmarked "For AEFI Investigation" in a separate Cold Chain Equipment ($+2^0$ to $+8^0$C) under special custody and in the knowledge of Medical Officer. This vial should never be issued to anyone unless authorized by DIO.

Health workers must be able to distinguish between vials that can be used in subsequent sessions and vials that must be discarded. Training and supervision materials should be revised to reflect the policy change.

B: *Cold chain maintenance during vaccine distribution:*

I. Maintain temperature of ILR between $+2^0$ to $+8^0$C for storage of vaccines & diluents and monitor temperature twice daily regularly including Sundays/holidays.
II. Note the name of the manufacturer, batch number and expiry date of the vaccine and diluent in the stock register.
III. Proper recording and reporting of vaccine distribution and usage has to be ensured.
IV. Keep stock up to date, don't over-stock or under-stock vaccines and diluent.
V. Multi-dose vials from which at least one dose has been removed may be at risk of contamination of the vial septum. These vials should therefore, never be allowed to be submerged in water (from melted ice for example) and the septum should remain clean and dry.

NOTE: Well-sealed conditioned icepacks should be used in vaccine carriers and water should not be allowed to accumulate where the vials are stored. Vaccine vials must be transported in properly locked plastic zipper bag.

VI. Observe early expiry first out (EEFO) policy for issuing vaccines. If the vaccines are of same expiry date, the partially used vaccine vials should be re-issued. The vial opened earlier, as recorded on the label of the vial, should be issued first.
VII. Contingency plan has to be in place in case of any exigency like power failure, equipment breakdown, etc.

C: *Cold chain maintenance during the immunization session:*

I. Inspect for and discard vaccine vial with visible contamination (i.e. checking for any change in the appearance of vaccine or any floating particles) or breaches of integrity (e.g. cracks, leaks).
II. All vaccines vials must be marked with date & time of opening at first use.
III. Note the name of the manufacturer, batch number and expiry date of the vaccine and diluent in the tally sheet.
IV. Always pierce the septum with a sterile needle/adapter for drawing vaccine from the multi-dose vials being used. OPV vial dropper should be recapped with stopper (small cap) after each use, and kept on the icepack.

D: *Specific attention while implementing open vial policy:*

I. Open Vial Policy is **NOT applicable** to opened reconstituted vials of **MR and BCG.**
II. Open Vial Policy is **NOT applicable** to opened vials of **Rotavirus vaccine with VVM on Cap.**
III. All vaccine vials have VVM appropriately displayed on them. The vaccine has to be used before reaching the end point.

Start point		Square lighter than circle. If the expiry date has not passed, USE the vaccine.
Discard point		Square matches the circle. Do NOT use the vaccine.
Beyond discard point		Square darker than the circle. Do NOT use the vaccine.

IV. If any AEFI occurred following use of any of the vial, do not use that vial, mark it and retain safely for AEFI investigation.

E: *After immunization session is over:*

I. ANM should segregate all the vaccine vials (used and unused) and keep it inside in a properly sealed zipper pouch/bag in the vaccine carrier under the cold chain (reverse cold chain) and ensure Vaccine carrier is picked up by the alternate vaccine delivery mechanism (AVD) to deliver at the designated Cold Chain point. All the vials used/unused/partially used including the empty vial must be returned to CCP.
II. Under no circumstance, the vaccine carrier/vaccines will be kept in the field (at places other than designated cold chain point; ANM/LHV/other health worker/ASHA/AWW house etc). In such an instance, the vials should be discarded and not used for subsequent sessions.

F: *At the Vaccine storage/cold chain point at the end of Immunization day:*

I. Cold chain handler should ensure appropriate segregation of the vaccines into opened and unopened vials, and follow the instructions as below:
   - **Unopened vials:**

     1. If VVM is intact and in usable stage, retain the vial in ILR as per guideline, and issue accordingly.
     2. If VVM is not in usable stage or there is partial/complete defacement of the label, retain the vial in a plastic box clearly marked "Not to be used" in a separate Cold Chain Equipment ($+2^0$ to $+8^0$C). Such vial should be discarded after 48 hours or before the next session whichever is earlier.

- **Opened vials:**

1. Segregate the vials on which Open Vial Policy is not applicable such as BCG/MR/RVV-with VVM on the Cap, retain in a plastic box clearly marked "Not to be used" in a separate Cold Chain Equipment (+20 to +80C). These vials should be discarded after 48 hours or before the next session whichever is earlier. In case of any reported AEFI they will not be discarded but retain in proper cold chain for investigation.
2. Segregate the vials for which Open Vial Policy is applicable such as OPV/Td/DPT/Hepatitis-B/Pentavalent/IPV/PCV/JE/RotaVac with VVM on Label as below:

    a. If VVM is intact and is in usable stage, retain the vaccine vial in ILR as per guideline subjected to condition that vial is within 28 days of opening (as found from date marked on the vial) and reissue in the next session after ensuring that it has not passed 28 days of opening the vial.
    b. If VVM is intact and is in usable stage, but the vaccine vial has crossed 28 days of opening (as found from date marked on the vial). These vials should be discarded after ascertaining that these vials are not required for AEFI investigation.
    c. If VVM is not in usable stage or there is partial/complete defacement of the label, retain in a plastic box clearly marked "Not to be used" in a separate Cold Chain Equipment ($+2^0$ to $+8^0$C). These vaccine vials should be discarded after 48 hours or before the next session whichever is earlier.

3. If there is any vial which has been used and there is report of AEFI, that vial (even if it is in usable stage) has to be kept separately in proper cold chain and properly sealed zipper bag earmarked "For AEFI Investigation" in a separate Cold Chain Equipment ($+2^0$ to $+8^0$C) under special custody and in the knowledge of Medical Officer. This vial should never be issued to anyone unless authorized by DIO.

II. The Cold chain handler should document the return of used (complete/partial) and un used vials in the vaccine distribution register.

Annexure-III: SOP for new Rotavac (dose) material with VVM on label for eVIN

1. Edit existing Rotavac (dose) material in eVIN to **'Rotavac (dose) Cap-VVM'** *(will be done by the eVIN IT team at National level)*
2. Add new material **'Rotavac (dose) Label-VVM'** under RI Vaccines *(will be done by the eVIN IT team at National level)*
3. Add **'Open Rotavac (vial) Label-VVM"** under Open vials. *(will be done by the eVIN IT team at the National level)*
4. Once all the changes related to the materials are completed, the users will have to log out and log in the web/mobile app for changes to reflect in the web/mobile application.
5. The users will transfer the identified existing batches **(VVM on label)** of Rotavac (dose) to **'Rotavac (dose) Label-VVM'** using stock edit.
    a. Make the stock of identified existing batch - 'zero'
    b. Add the same batch and stock using stock edit in the new material created i.e. **Rotavac (dose) Label-VVM**
    c. The DIOs to ensure that this transfer is completed in their districts.
6. Once all the batches with VVM on label are transferred to the new material, the subsequent stock entry for Rotavac with VVM on label to be entered **under Rotavac (dose) Label-VVM).**
7. The open vials of Rotavac vaccines (VVM on label) are to be entered in new material **'Open Rotavac (vial) Label-VVM"** under Open vials.
8. It is desired that the Rotavac with VVM on the cap already available in the state should be exhausted completely following the EEFO and then only the **"*New presentation of Rotavac with VVM on the Label*"** should be supplied.
9. The existing batches of Rotavac vaccine with VVM on cap to be consumed on priority. **The open vial policy is not applicable for the older material 'Rotavac (dose) Cap-VVM'.**
10. Once all the batches of VVM on Cap are consumed, the material **'Rotavac (dose) Cap-VVM'** will be removed from eVIN and the system. *(will be done by the eVIN IT team at National level)*
11. The higher stores (DVS) should not supply both the types of Rotavac vaccines to a same cold chain point as far as possible. The Cold chain handler should preferably not send both the types of materials to the same session site to avoid confusion among the vaccinators regarding open vial policy.
12. Track the consumption of both the types of Rotavac Vaccines (DIOs).
13. Train the Cold Chain Handlers on the open vial policy for the newer Rotavirus vaccine and the new SOP for entry into eVIN (DIOs).