

**OFFICE OF THE DIRECTOR GENERAL
DRUGS & COPYRIGHTS, DRUGS CONTROL ADMINISTRATION
VENGALRAONAGAR, HYDERABAD**

Cir.Memo.No.1126/STC/2016

Dated: .03.2016

Sub: Drugs & Cosmetics Act, 1940 and Rules made there under – National "Switch of tOPV to bOPV on 25th April 2016 – Certain instructions issued – Regarding.

- Ref: 1. Memo.Rc.No.1126/STC/2016, dt:25.03.2016 of Director General, Drugs & Copyrights, Drugs Control Administration, Hyderabad.
2. D.O.Lr.No107/JD(CH&I)/2016, dt: .03.2016 of the Special Commissioner of Health and Family Welfare, A.P. Workshop held on 31.03.2016 at the Secretariat, Health, Medical & Family Welfare Department addressed by the Principal Secretary to Government and the Special Commissioner of Health and Family Welfare, Government of Andhra Pradesh, Hyderabad.

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What is the SWITCH ?

The trivalent Oral Polio Vaccine (tOPV) currently being used contains all three types of attenuated polioviruses – type 1, 2 and 3. The last case of wild poliovirus (WPV) type 2 was reported in 1999 and the global eradication of type 2 WPV has been declared by the Global Certification Commission of World Health Organization on 20th September 2015. Therefore, now there is no need to include type 2 in OPV.

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Accordingly, as part of the "Global Polio Eradication and Endgame Strategy 2013-18", all OPV using countries across the world will switch from trivalent to bivalent vaccine (which contains only type 1 and 3) in globally coordinated manner in April 2016. All tOPV stocks will be withdrawn, replaced and destroyed in a globally coordinated switch within a two week window in April 2016.

When is the SWITCH ?

In India, the National Switch Day will be 25th April 2016, when tOPV will be completely withdrawn and replaced by bOPV in routine immunization and polio campaigns.

Before the SWITCH:

Control the supply of tOPV to avoid wastage. The tOPV supply will be controlled and balanced to minimize excess stock of tOPV and wastage during the SWITCH.

bOPV stocks shall be made available and supplied. But they should not be opened and used before the SWITCH date i.e. 25.04.2016.

On the SWITCH day:

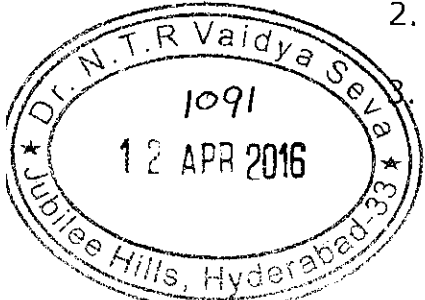
25th April 2016 is National Switch Day in India.

All remaining tOPV to be collected / returned to supplier / manufacturer.

- Stock of bOPV is to be made available.
- Certificate from all the concerned stating that there is no tOPV left with them.
- Disposal of left over trivalent Oral Polio Vaccine.

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Disposal of remaining inventories of tOPV:

What should happen to the unused supplies or inventories of tOPV after the global switch to bOPV?

After the switch date, all remaining tOPV supplies or stocks should be collected from both public and private facilities and destroyed. There are several ways to dispose of unused tOPV vials:

- a. by encapsulation and disposal in a landfill site,
- b. direct disposal in an engineered landfill site,
- c. or through incineration in high - or medium - temperature incinerators.

Why do unused supplies or inventories of tOPV need to be destroyed immediately after the switch?

The accidental or deliberate use of tOPV after the switch could cause outbreaks of cVDPV2, particularly because the number of individuals susceptible to infection with poliovirus type 2 will increase after the switch. Destroying all tOPV will eliminate the risk of such cVDPV2 outbreaks.

After the SWITCH:

"Switch" validation for complete removal and destruction of tOPV.

Action Plan:

In view of the above, all the Drugs Inspectors / Assistant Directors in the State are instructed:

1. To sensitize all the stake holders and conduct meetings with them i.e. Vaccine dealers / Pediatricians / Nursing Homes etc.
2. To be in touch with and coordinate with District Immunization Officer concerned by attending meetings with DM&HO, Deputy DM&HO, Pediatricians Vaccine Stockists etc. and taking action as per plan pertaining to switch over programme from tOPV to bOPV.
3. To identify the Vaccine stockists / dealers in their jurisdiction and to obtain stock position and distribution particulars of tOPV from them.
4. To identify private places of vaccination to ensure effective withdrawal of unused tOPV and availability of bOPV on switch date.
5. The Drugs Inspectors have to prepare action plan for their areas and Assistant Directors for their districts.
6. To ensure that tOPV is sold by the stockist to Hospital / Registered Medical Practitioner in a limited quantity such that it should be utilized before 24.04.2016. However, tOPV should be made available with the needy Hospitals and Pediatricians till 24.04.2016 for immunization of babies.
7. To give necessary instructions to all the vaccine dealers so as to call back the un utilized tOPV and return the same to the supplier / manufacturer under intimation to the area Drugs Inspector.
8. To ensure that the vaccine dealers take all necessary steps to make bOPV available with them by 11.04.2016. Further the dealer should take enough precautions to see that the stocks of bOPV are sold and reached to the Hospitals / Private Nursing Homes / Pediatricians / Registered Medical Practitioner only by 25.04.2016 but not before.

9. To give instructions to the stockists to sell only bOPV on / after 25.04.2016 and **should not distribute tOPV after 25.04.2016 at any cost.** If any stockist sells / distributes tOPV after 25.04.2016 serious action will be initiated against the dealers.
10. To give necessary information to the Pediatricians / Gynecologists / Doctors / IMA not to use tOPV after 24.04.2016 and they can use only bOPV from 25.04.2016 along with IPV.
11. To coordinate with the District Immunization Officer to recall the partly used / opened tOPV vials / bottles from Private Doctors / Nursing Homes on 25.04.2016 and to follow the safe disposal programme in coordination with District Immunization Officer by identifying a suitable place for disposal by approved means.
12. To give notices to all concerned on the above points and obtain acknowledgment.
13. To obtain certificate of withdrawal / return of unutilized / partly utilized tOPV from all the concerned stake holders.
14. To issue validation certificate of complete withdrawal of tOPV in their jurisdiction.
15. Take any other necessary measures as deemed fit to ensure effective switch of tOPV to bOPV on 25th April 2016.
16. To submit weekly reports to the head office on the progress of the plan on the above lines.


Dr.A.RAVI SHANKAR, IPS
DIRECTOR GENERAL
DRUGS & COPYRIGHTS

To:

All the Assistant Directors / Drugs Inspectors in the State.

Copy to:

All the Deputy Directors in the State for information and necessary action.

The Joint Directors / Director for information and necessary action.

The Joint Director (CH&I), O/o Commissioner of Health & Family Welfare, Government of Andhra Pradesh, Hyderabad for information and necessary action.

The Special Commissioner, Health and Family Welfare, Government of Andhra Pradesh, Hyderabad for information.

The Principal Secretary to Government, Health, Medical & Family Welfare Department, Government of Andhra Pradesh, Hyderabad for information.

✓ The Chief Executive Officer, Dr.NTR Vaidya Seva, Government of Andhra Pradesh, Hyderabad for information with a request to communicate to all empanelled networking hospitals in the state.

The Indian Academy of Pediatrics, Andhra Pradesh Branch, Hyderabad for information and necessary action.

The Andhra Pradesh Medical Council, P.B.523, Sultan Bazar, Near Post Office, Opp Womens College, Hyderabad, Telangana-500095 for information and necessary action.

Dr.P.Susila, Hon'ble Secretary, Vijayawada Obstetric & Gynecological Society, D.No.29-14-58, Lalitha Super Specialities, Prakasham Road, Surva