

F. No. X11026/85/15-BD
Directorate General of Health Services
O/o Drugs Controller General (I)
(Biological Division)
FDA Bhawan, Kotla Road, New Delhi

Dated: 23-03-2016

Office Memorandum

Sub: Preparation for global switch from tOPV to bOPV - regarding.

As directed by the Ministry of Health & Family Welfare through minutes of meeting dated 18.12.2015 for achieving the switch from tOPV to bOPV on 25.04.2016 in immunization programme as per global polio end game plan adopted by World Health Organisation, it is requested that:

1. Product permission for manufacturing or import of tOPV shall be considered as cancelled after 24.04.2016 and
2. tOPV existing any where including in supply chain shall be caused to be destroyed by 24.04.2016.

A copy of minutes of meeting is annexed herewith for information and necessary action by all concerned.

As the matter is of very high global and national importance, a co-operation/involvement of all stakeholders is solicited on top priority.


(Dr. G. N. Singh)
Drugs Controller General (India)

To,

1. All State Licensing Authorities
2. M/s. Bharat biotech International Ltd, Genome Valley, Turka-pally (V), Shameerpet Mandal, Ranga Reddy District, Hyderabad
3. M/s. Biological E., Plot No.1, S.P. Biotechnology Park, Phase-II, Kolthur Village, Shameerpet Mandal, Rangareddy District, Hyderabad.
4. M/s. Biomed Pvt. Ltd, C-96, B.S. Road, Industrial Ropad, Ghaziabad-201009
5. M/s. Panacea Biotec Ltd, Malpur, Baddi, PO Bhud, Tehsil, Nalagarh, Distt. Solan, (H.P)
6. M/s. Serum Institute of India Pvt. Ltd., 212/2, Hadapsar, Pune- 411028
7. M/s. Shantha Biotechnics Ltd. survey No. 274, Athvelli Village, medchalMandal, Ranga Reddy, District- 501401
8. M/s. Bharat Immunological & Biological Corporation Ltd. (BIBCOL), village- Chola, Dist- Bulandshahr, U.P
9. M/s. Hallkine Bio Pharmaceutical Corporation Ltd., Acharya Donde Marg, Parle, Mumbai- 400012
10. M/s. Sanofi Pasteur India Pvt Ltd, 54/A Sir Mathurdas Vasanji Road, Andheri East, Mumbai - 400 093.
11. All Zonal, Sub-zonal & Port Offices of CDSCO.
12. Central Drugs Laboratory, Central Research Institute, Kasauli - 173 204 (H.P.)
13. Joint Secretary (R), MoHFW, Government of India, Nirman Bhawan, New Delhi.
14. Dr. Pradeep Halder, Deputy Commissioner (I), MoHFW, Government of India, Nirman Bhawan, New Delhi.
15. World Health Organisation-SEARO, World Health House, Indraprastha Estate, M G Marg, New Delhi-02

PPS to

- (I) Sect H&FW
- (II) DGHS
- (III) TCR

Ministry of Health & Family Welfare
Immunization Division

Minutes of the meeting for tOPV to bOPV switch

A meeting to discuss tOPV to bOPV switch was held on 18th December 2015 at 3:30 p.m. under the chairpersonship of AS&MD (NHM) in Room No. 249-A, Nirman Bhawan, New Delhi. The meeting was attended by senior officials from Ministry, representatives from WHO-SEARO, WHO-India, UNICEF, CDSCO, CDL Kasauli, INCLN, IMA and vaccine manufacturers. The list of participants is annexed in Annexure I.

The meeting initiated with welcome note by AS&MD (NHM) highlighting the importance of each partner in tOPV to bOPV switch and requesting them to fully support the Govt. of India in the successful implementation of switch.

A powerpoint presentation was made by DC (I) highlighting the timeline of switch and role of various stakeholders and validation of switch.

Key issues and discussion points

- 1) The country has decided 25th April, 2016 as National Switch Date. After the switch date only bOPV will be used, both in routine immunization as well as polio campaigns. No supplies of tOPV will be accepted from 1st March 2016 onwards in Government supply chain and after 1st April 2016 in private market. After switch date, remaining tOPV will be removed from cold chain and disposed as per National Switch Plan National Validation Day has been decided as 9th May, 2016.
- 2) After 16th July 2016, no facility (including vaccine manufacturers and testing labs) other than the designated essential facility for India - NIV Pune- to retain any Sabin type 2 containing material including tOPV.
- 3) Communication materials for the switch will be provided by MoHFW to stakeholders, so that uniform message is conveyed across the country.

4) Role of DCG(I)

DCG(I)

- ① • DCG(I) to communicate with vaccine manufacturers and drug controllers at Zonal and District level to ensure availability of bOPV two weeks prior to switch. It must be ensured that secondary packaging of bOPV is not opened before switch date.
- ② • DCG(I) to cancel all licenses for manufacturing as well as import of tOPV for use from 25th April 2016 onwards.
- ③ • DCG(I) to issue necessary communication to prohibit the use/storage of tOPV and ensure destruction of existing stock of tOPV in private market after the switch day.
- ④ • DCG(I) to issue necessary advisory to vaccine manufacturers and testing labs for destruction of remaining tOPV bulks, tOPV control samples and batches on stability program after switch date.
- ⑤ • DCG(I) to issue necessary instructions to clearing and forwarding agencies so as to allow the supply of tOPV to dry up and to build up supply of bOPV in view of switch date.

Annexure- 1

List of Participants:

1. Mr. C.K. Mishra, AS & MD (NHM), MoHFW
2. Dr. Rakesh Kumar, JS (RCH), MoHFW
3. Dr. Pradeep Halder, DC (I) , MoHFW
4. Dr. MK Aggarwal, DC (UIP) , MoHFW
5. Dr. VG Somani, Joint Drug Controller, CDSCO
6. Dr. Arun Bharadwaj, Director,CDL Kasauli
7. Mr. Vikas Arya, Director (Procurement), MoHFW
8. Dr. NK Arora, INCLIN Trust
9. Dr. Sunil Bahl, SEARO-WHO
10. Dr. A. Marthanda Pillai, IMA
11. Dr. Pankaj Bhatnagar, WHO-NPSP
12. Dr. Gagan Gupta, UNICEF-India
13. Dr. K.K. Aggarwal, IMA
14. Dr. SR Bhalla, CDL Kasauli
15. Mr. Shiv Kumar, CDSCO
16. Dr. Danish Ahmed, WHO-India
17. Dr. NV Kamat, IMA
18. Dr. Satish Gupta, UNICEF-India
19. Ms. Geetali Trivedi, UNICEF
20. Mr. Bhawani Shankar Tripathy, UNICEF-India
21. Representatives of Panacea Biotech
22. Representatives of Haffkine Bio-pharmaceutical Corporation Ltd
23. Representatives of Serum Institute of India
24. Representatives of Sanofi
25. Representatives of Biomed
26. Representatives of BIBCOL
27. Representative of Bharat Biotech did not participate but committed to follow up meeting decisions via their letter.
28. Dr. Pankaj Agrawal, Technical Officer-Immunization Division, MoHFW
29. Dr. Yashika Negi, Technical Officer-Immunization Division, MoHFW
30. Dr. Sheenu Chaudhary, Technical Officer-Immunization Division, MoHFW
31. Dr. Priti Chaudhary, Technical Officer-Immunization Division, MoHFW
32. Ms. Eena Lamba, Program Assistant-Immunization Division, MoHFW