

Guidelines for the Public Private partnership Model of ART centres

Background

The Department of AIDS Control (DAC), Govt of India, is providing free first line Antiretroviral treatment (ART) to persons living With HIV/AIDS to PLHAs in India through designated public hospitals as per the guidelines recommended by the National AIDS Control Organisation (NACO) from time to time; **It** coordinates the provision of ART at designated public hospitals by limiting the selection, procurement, distribution and rational use of drugs, including antiretroviral drugs, and prescribing guidelines for treatment of opportunistic infections and provision of ART

DAC is desirous of extending the provision of ART to more PLHAs in collaboration with not-for-profit non-governmental organisations as well. These collaborations shall be with the Corporate Organizations registered under the Companies Registration Act/or a PSU. It encourages the establishment of an ART centre to extend HIV/AIDS related treatment, care and other services to its employees and their families living with HIV/AIDS and to extend these services to PLHA's in the nearby areas as a part of their Corporate Social Responsibility (CSR)

Public Private Partnership

The purpose of this Public private partnership (PPP) is to initiate/continue the collaborative ART programme between DAC and Corporate sectors/ PSU (Private partners) for provision of high quality provision of ART and associated healthcare and medical management of PLHAs in the country.

II. RESPONSIBILITIES OF DAC

- 1) DAC shall organize induction/ refresher training or provide support for training of personnel of PRIVATE PARTNER involved in the collaborative ART centre.
- 2) DAC shall provide to PRIVATE PARTNER regular updates on National ART guidelines from time to time as earlier.
- 3) DAC and PRIVATE PARTNER shall form a committee comprising of representative from DAC, CEO / Director of PRIVATE PARTNER, which shall supervise and monitor the collaborative ART programme to ensure provision of quality services.
- 4) DAC/SACS will continue to provide ARV drugs on a [three] monthly basis on receipt of a requisition/s from PRIVATE PARTNER and certificate of utilization of drugs in a prescribed format supplied earlier.

III. RESPONSIBILITIES OF PRIVATE PARTNER

- 1) PRIVATE PARTNER has to set up a centre at *their site* and to appoint a Nodal officer, as the official contact for the collaborative ART Programme.
- 2) PRIVATE PARTNER shall provide all health services related to provision of ART and treatment of opportunistic infections, including those listed in Annexure I, free of cost to patients who require treatment. PRIVATE PARTNER shall not deny services to any person living with HIV on any ground.
- 3) PRIVATE PARTNER represents that it provides various health services to PLHAs, a description of which is set out at Annexure II.
- 4) PRIVATE PARTNER will comply with all the laws for the time being in force in India in the running of the ART centre as done earlier. PRIVATE PARTNER

has to obtain all necessary government approvals and to appoint the necessary staff with the requisite technical qualifications.

- 5) PRIVATE PARTNER strictly follows the National ART guidelines (drug regimen as well as physical standards) issued by DAC from time to time, follow the terms of reference for staff including qualifications as specified by DAC and has ensured that mechanisms needed for good treatment adherence are in place.
- 6) PRIVATE PARTNER shall respect the autonomy and privacy of the patients and to this end provides pre- and post-test counselling, obtains written informed consent from the patient prior to a test or treatment, and maintains confidentiality of the patients on the principle of shared confidentiality.
- 7) PRIVATE PARTNER shall provide for data protection systems to ensure that the confidential records of the patients are computerized and are protected so that they are not accessible to any unauthorised person.
- 8) PRIVATE PARTNER shall provide a copy of all medical records to the patients on their request.
- 9) PRIVATE PARTNER shall maintain all the registers and reporting formats as per DAC ART guidelines. They will send report of all adverse drug reactions to DAC.
- 10) PRIVATE PARTNER shall use standard DAC Monitoring and Evaluation tools.
- 11) PRIVATE PARTNER shall provide standard, regular monthly reports of patient numbers and relevant details for the previous month to DAC by the 4th of each month in prescribed formats in accordance with the guidelines laid down by DAC from time to time. DAC will be free to use the data so sent to them in an anonymous manner.

- 12) PRIVATE PARTNER shall provide details of the ART team at their centre along with the names and technical qualifications of the staff in case of any change to DAC from time to time.
- 13) PRIVATE PARTNER shall entirely bear the costs related to the staff's salary (doctors, counsellors, pharmacist, nurses, medical records officer and administrative staff) and the cost related to the infrastructure. PRIVATE PARTNER represents that it has enough funds to run the programme for the next three / five years. PRIVATE PARTNER will permit DAC to inspect its documents relating to the balance sheets, profit and loss accounts, grants and donors, financial and other documents so that DAC can verify the representation of sustainability of the collaborative ART programme.
- 14) PRIVATE PARTNER has to establish a network with NGOs involved in HIV care and support as well as with the Indian Network for People Living with HIV/AIDS or PLHA groups in the area for increasing access to treatment and for follow-up support.
- 15) The designated representatives of PRIVATE PARTNER shall continue to attend the coordination meeting with DAC at their own costs.
- 16) PRIVATE PARTNER shall not permit research or clinical trial, whether relating to the allopathic system of medicine or any alternate system of medicine or any combination thereof, at the designated ART centre, except with the approval of the Drugs Controller General of India for the conduct of such clinical trial. Further, in the event of an approved clinical trial, the Party of the Second Part will ensure that ethical protocols are complied with.
- 17) Use of any data obtained by PRIVATE PARTNER during the course of its collaborative ART programme shall be done in an anonymous manner such that the identity of the patients enrolled at the collaborative ART programme is not revealed in any manner.
- 18) PRIVATE PARTNER shall maintain the records for a period of five years from the time of the Agreement is terminated or lapses by efflux of time.

- 19) PRIVATE PARTNER shall constitute a grievance Redressal mechanism. *[A model grievance Redressal mechanism is at Annexure III.]* Further, PRIVATE PARTNER shall forward to DAC in an anonymous manner the nature of complaints received and action taken thereon on a monthly basis.
- 20) PRIVATE PARTNER shall continue to provide space, CD4 machine (or linkage) and staff for the ART center.
- 21) PRIVATE PARTNER will conduct baseline investigations free of cost for all PLHIV and sophisticated tests at concessional rate for persons attending ART center.
- 22) In case of severe OI needing inpatient care, the patients may be treated at their own Hospital or to be referred to other hospital for better care and treatment.

IV. COMMENCEMENT of ART services

The commencement of art services happens only after the MoU in the form of a signed agreement between the DAC and the private partner.

V. RENEWAL OF AGREEMENT

- 1) The Agreement is renewable at the option of DAC and PRIVATE PARTNER.
- 2) Six months prior to the expiry of the Agreement due to efflux of time DAC shall intimate PRIVATE PARTNER if it intends to renew or not to renew the Agreement.
- 3) In the event that PRIVATE PARTNER decides not to renew the Agreement, PRIVATE PARTNER shall intimate three month in advance to DAC about its inability to continue to provide treatment free of charge to the patients enrolled. If PRIVATE PARTNER fails to continue to provide treatment free of

charge or expresses its inability to do so, they shall give notice to the patients and DAC about this and refer the patients to the nearest government hospital providing treatment for opportunistic infections and ART, as directed by DAC. Further, upon such referral, PRIVATE PARTNER shall forthwith forward a copy of all medical records of the patients to such hospital and to DAC or a person designated by DAC to receive such medical records. Thereupon, DAC will be responsible for ensuring that the patients continue to receive the drugs.

- 4) In the event that DAC desires to renew the Agreement, the terms and conditions of this Agreement, as may be amended, will apply *de novo*. It is made expressly clear that in that event, PRIVATE PARTNER will have to re-apply for and re-obtain certification.
- 5) Both parties shall ensure that there is no treatment interruption of the patients.

VI. TERMINATION OF AGREEMENT

- 1) The PRIVATE PARTNER shall ensure that the infrastructure and manpower at centre is provided as per operational guidelines and in event of any deficiencies / reduction/withdrawal of space or staff, DAC(GOI) will exercise its option to terminate the agreement unilaterally
- 2) Any party may terminate this Agreement without giving any reasons after giving three months notice to the other party at the address provided in this Agreement for correspondence or the address last communicated for the purpose and acknowledged in writing by the other party.
- 3) On such notice of termination being received by any party, PRIVATE PARTNER shall intimate DAC about its inability to continue to provide treatment free of charge to the patients enrolled. If PRIVATE PARTNER cannot continue to provide treatment free of charge, they shall give notice to the patients and DAC about this and refer the patients to the nearest government hospital providing treatment for opportunistic infections and

ART, as directed by DAC. Further, upon such referral, PRIVATE PARTNER shall forthwith forward a copy of all medical records of the patients to such hospital and to DAC or a person designated by DAC to receive such medical records. Thereupon, DAC will be responsible for ensuring that the patients continue to receive the drugs.

VII. BREACH BY PRIVATE PARTNER

- 1) In case PRIVATE PARTNER is not able to provide services as per agreement or defaults on the provision of this Agreement or declines the patients to provide medication or directly or indirectly makes any charges for the treatment of opportunistic infections or ART or otherwise enters into any malpractices, it shall be liable for breach of agreement and breach of trust and other consequences which may include black listing with DAC, MOHFW, Ministry of Home affairs and External Affairs. This action shall also be intimated to their parent/ International NGO also for necessary action by them.
- 2) If PRIVATE PARTNER is found to have made any charges for the treatment which was to be given free of charge under this Agreement or to have not provided the medicines to the named patients or to have otherwise misappropriated the funds or goods released by DAC to PRIVATE PARTNER, then without prejudice to any other right or consequence or mode of recovery, DAC may recover the amount thereof from PRIVATE PARTNER and/or its office bearers as arrears of land revenue.

VIII. SETTLEMENT OF DISPUTES

1. Any dispute or difference or question arising at any time between the parties hereto arising out of or in connection with or in relation to this Agreement shall be referred to and settled by arbitration under the provisions of the Arbitration and Conciliation Act, 1996 or any modification or replacement thereof as applicable for the time being in India.

2. The arbitration shall be referred to an arbitrator nominated by Secretary Department of Legal Affairs, Ministry of Law and Justice, Govt. of India Delhi. The Arbitrator may, if he so feels necessary, seeks opinion of any health care personnel with experience of working in the field of HIV and care and treatment of PLHAs.
3. The place of arbitration shall be either New Delhi or the site of the collaborative ART programme, which shall be decided by the arbitral tribunal bearing in mind the convenience of the parties.
4. The decision of the arbitrator shall be final and binding on both the parties.

LAW APPLICABLE

The Agreement shall be construed and governed in accordance with the laws of India.

Assistance to ART Centres in various sectors under NACP_ IV						
Component	Public Health Sector	Other Govt. Sector	PSUs	Corporate Sector	NGOs	Remarks
	Medical Colleges, Dist. Hosp.	Railways, Defence, ESI, Paramilitary etc.	GOI undertakings	Criteria as per scheme	Criteria as per scheme	
Land	X	X	X	X	X	Only for new constructions
Infrastructure Development	√	X	X	X	X	Under NACP-III
Equipment (CD4 machine)	√	X	X	X	X	
Additional Human Resources	√	*	X	X	X	* Only counsellor if patients > 1000
Diagnostic Kits (HIV/CD4)	√	√	√	√	√	
ARV Drugs (First Line)	√	√	√	√	√	
Drugs for Opportunistic Infections	√	√	√	√	√	
Training of key personnel	√	√	√	√	√	TA/DA by sponsoring agency
IEC material	√	√	√	√	√	
Operational Costs	√	√	X	X	X	

√-by NACO

X- By Private Partner

Annexure I

LIST OF DRUGS TO BE PROVIDED BY DAC TO PRIVATE PARTNER

S.no	LIST OF ARV DRUGS	OI DRUGS
	Adults	Metronidazole 400mg
1.	Zidovudine300mg + Lamivudine 150mg	Albendazole 400m
2	Zidovudine300+Lamivudine150+Nevirapine200	Ciprofloxacin 500mg
3	Tenofovir 300 mg+ Lamivudine 30 mg	Prednisolone 10mg
4	Nevirapine tablet/Suspension 200 mg/50 mg	Nitazoxanide 500mg
5	Efavirenz 200 mg, 600 mg	TMP-SMX SS (80/400 mg)
6.	Lopinavir 400 mg /ritonavir 100 mg	TMP-SMX DS (160/800mg)
7	Stavudine 30mg + Lamivudine 150mg	Cotrimoxazole Suspension
8.	Stavudine30+Lamivudine150 + Nevirapine 200	Azithromycin 500mg
9	Atazanavir 300 mg/ ritonovir 100mg	Fluconazole 150mg& 400 mg
	Paediatric	Clotrimazole Ointment
10	Tablet.Zidovudine 60+ Stavudine 30	Clindamycin 300mg
11	Tablet.Zidovudine 60+ Lamivudine 30+Nevirapine 50	Acyclovir 400mg
12	Tablet.Abacavir 60+ Lamivudine30	Cefotaxime 1g
13	Tablet.Efavirenz 50 mg	Ethambutol 800mg
14	Lopinavir/ ritonovir 100/25 tablet	GanciclovirTablets500mg 1000mg
15	Lopinavir / ritonovir syrup	Tab. Levofloxacin 500mg
16	Stavudine 6 + Lamivudine (Disp Tab)	Flucanazole IV 200mg
17	Stavudine 6 + Lamivudine + Nevirapine (Disp.Tab)	Inj Ganciclovir 500mg,
18		Itraconazole 200mg
19		Clarithromycin 500mg
20		Syrup Flucon 350 mg
		Nitazaxonide 100 mg Syp

Annexure II

MODEL OF DESCRIPTION OF SERVICES PROVIDED / PROPOSED TO BE PROVIDED

Address of site	XXYYZZ – Address
Outpatient	
Days	Monday to Saturday
Timings	09.00 am to 04.00 pm(As per hospital timings)
Inpatient care	
Number of patients registered	
Number of patients receiving ART	
Average number of patients attending OPD everyday	
Criteria followed in administering ARVs	As per DAC Guidelines
Treatment for OIs	As per DAC Guidelines
First line regimen	AZT/TDF+ 3TC+ NVP/EFV
Description of follow-up of patients	As per DAC Guidelines
Facilities available	As per DAC Guidelines for ART Center
Personnel and their qualifications	As per DAC Guidelines for ART Center

ANNEXURE- III

MODEL GRIEVANCE REDRESSAL MECHANISM

[Note: This portion has been taken from the draft law on HIV/AIDS and it would be advisable for PRIVATE PARTNER to constitute a grievance Redressal mechanism at the outset.]

- (a) PRIVATE PARTNER shall appoint a person of senior rank, working full time in the organisation, as the Complaints Officer, who shall, on a day-to-day basis, deal with complaints received from an aggrieved person or an authorised representative of such person.
- (b) Every aggrieved person or an authorised representative of such person, who has a grievance against the PRIVATE PARTNER about the services provided or refused, has the right to approach the Complaints Officer to attend to such complaint and shall be informed of such rights by PRIVATE PARTNER.
- (c) The Complaints Officer may inquire *suo motu*, and shall inquire, upon a complaint made by any aggrieved person or authorised representative of such person, into the complaint.
- (d) The Complaints Officer shall act in an objective and independent manner when inquiring into complaints made.
- (e) The Complaints Officer shall inquire into and decide a complaint promptly and, in any case, within seven working days. Provided that in cases of emergency, the Complaints Officer shall decide the complaint within one day.
- (f) The Complaints Officer, if satisfied that there has been an unfair/arbitrary refusal of services or deficiency in the services provided, shall (I) first direct PRIVATE PARTNER to rectify the cause

of the grievance, (ii) then counsel the person alleged to have committed the act and require such person to undergo training and social service. Upon subsequent violations by the same person, the Complaints Officer shall recommend to PRIVATE PARTNER to, and the institution shall, initiate disciplinary action against such person.

- (g)** The Complaints Officer shall inform the complainant of the action taken in relation to the complaint.